

1 Month Followup - Pedimacs

Followup Status (1 Month Followup (+/- 7 days))

Select one of the following

- Inpatient
- Outpatient
- Other Facility
- Unable to obtain follow-up information

Follow-up date

Facility Type

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

State 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

Was patient intubated?

- Yes
- No
- Unknown

Was patient on dialysis?

- Yes
- No
- Unknown

Pump Change

Pump Exchange

- Yes
- No
- Unknown

If yes, please select one of the following:

- Intracorporeal device
- Para- or Extra- corporeal device
- Upsizing device because of patient growth status
- All other reasons would categorize the pump change as a Device Malfunction

Please select appropriate reason:

- Thrombus NOT associated with hemolysis
- Change in hemodynamics
- Clinical status
- Device parameters

Was there a Console Change?

- Yes
- No
- Unknown

Date of console change

ST= Unknown

Original Console Name

New Console Name

Medical Condition

NYHA Class

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

Ross Classification of Congestive Heart Failure

- Ross Class I: No limitations or symptoms.
- Ross Class II: No growth failure.
- Ross Class III: Growth failure.
- Ross Class IV: Symptomatic at rest.
- Not applicable: >= 2 years of age
- Unknown

Choose all indicated symptoms that apply.

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

Choose all indicated symptoms that apply.

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

Choose all indicated symptoms that apply.

- Tachypnea
- Retractions
- Grunting
- Diaphoresis
- Unknown

Functional Capacity

Sedated

- Yes
- No
- Unknown

Paralyzed

- Yes
- No
- Unknown

Intubated

- Yes
- No
- Unknown

Ambulating

Yes
 No
 Unknown

Primary Nutrition

Orally
 Per feeding tube
 TPN
 Not Applicable

Excursions

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

Yes
 No
 Unknown
 Not Applicable

If yes, where (please select all that apply)

Playroom
 Cafeteria
 Walk outside
 Sitting room
 General rehab
 None

ZONES

Hemolysis Zone

Please enter the peak Plasma-free hemoglobin (PFH) since the last visit:

ST= Unknown
 Not Done

What is your hospital's upper limit of the normal range of peak PFH?

ST= Unknown
 Not Done

Please enter the peak serum lactate dehydrogenase (LDH) since the last visit:

ST= Unknown
 Not Done

What is your hospital's upper limit of the normal range of LDH?

ST= Unknown
 Not Done

Enter the Maximum and Minimum HCT or HGB since the last visit.

Min. HCT:

ST= Unknown
 Not Done

Max. HCT:

ST= Unknown

Not Done

Min. HGB:

ST= Unknown

Not Done

Max. HGB:

ST= Unknown

Not Done

Highest Total Bilirubin since the last visit:

ST= Unknown

Not Done

Has the following been present at any time since the last visit?

Physical Findings (select all that apply):

Hemoglobinuria (Tea-Colored Urine)?

Yes

No

Unknown

Pump malfunction and/or abnormal pump parameters?

Yes

No

Unknown

Right Heart Failure Zone

Clinical Findings – Since the last visit.

CVP or RAP > 16 mmHg?

Yes

No

Unknown

Not Done

Dilated Vena Cava with absence of Inspiratory Variation by Echo?

Yes

No

Unknown

Not Done

Clinical findings of elevated jugular venous distension at least half way up the neck in an upright patient?

Yes

No

Unknown

Peripheral Edema?

Yes

No

Unknown

Ascites?

Yes

No

Unknown

Has the patient been on Inotropes since the last visit?

- Yes
- No
- Unknown

If yes, select all that apply:

- Dopamine
- Dobutamine
- Milrinone
- Isoproterenol
- Epinephrine
- Norepinephrine
- Levosimendan
- Unknown
- Vasopressin
- Nitroprusside
- Fenoldopam
- Prostacyclin

Nesiritide?

- Yes
- No
- Unknown

Has the patient had a RVAD implant since the last visit?

- Yes
- No
- Unknown

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

- Yes
- No
- Unknown

If yes, please enter the Modified Rankin Scale.

Modified Rankin Scale

- 0 – No symptoms at all
- 1 - No Significant disability: despite symptoms: able to carry out all usual duties and activities
- 2 - Slight disability: unable to carry out all previous activities but able to look after own affairs without assistance
- 3 - Moderate disability: requiring some help, but able to walk without assistance.
- 4 - Moderately severe disability: unable to walk without assistance, and unable to attend to own bodily needs without assistance.
- 5 - Severe disability: bedridden, incontinent and requiring constant nursing care and attention.
- 6 - Dead

ST= Not Documented

Not Done

1 Month Followup - Pedimacs

Hemodynamics

General Hemodynamics

Systolic blood pressure mmHg

ST= Unknown
 Not done

Diastolic blood pressure mmHg

ST= Unknown
 Not done

Mean Arterial Blood Pressure (MAP) mmHg

ST= Unknown
 Not done

ECG rhythm

- Sinus
 Atrial fibrillation
 Atrial Flutter
 Paced: Atrial pacing
 Paced: Ventricular pacing
 Paced: Atrial and ventricular pacing
 Unknown
 Not done
 Other, specify

Height in

cm

ST= Unknown
 Not done

Weight lbs

kg

ST= Unknown
 Not done

Invasive Hemodynamics

Date of Measurement

ST= Unknown
 Not Done

Pulmonary artery systolic pressure mmHg

ST= Unknown
 Not Done

**Pulmonary artery
diastolic pressure**

mmHg

ST= Unknown
 Not Done

Mean RA Pressure

mmHg

ST= Unknown
 Not Done

PVR

wood units

ST= Unknown
 Not Done

**Mean Pulmonary artery wedge
pressure**

mmHg

ST= Unknown
 Not Done

Central venous pressure (CVP)

mmHg

ST= Unknown
 Not Done

Cardiac Index

L/min/M² (by Swan)

ST= Unknown
 Not Done

**Was Cardiac Index Measured by
Fick or Thermodilution?**

Yes
 No
 Unknown

Choose Method

Fick
 Thermodilution

1 Month Followup - Pedimacs

Medications

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

ACE inhibitors Yes
 No
 Unknown

Aldosterone antagonist Yes
 No
 Unknown

Amiodarone Yes
 No
 Unknown

Angiotensin receptor blocker drug Yes
 No
 Unknown

Antiplatelet therapy drug Yes
 No
 Unknown

Select drug(s) Aspirin
 Dextran
 Dipyridamole
 Clopidogrel
 Ticlopidine
 Unknown
 Other, specify

Thrombolytic Yes
 No
 Unknown

Beta-blockers Yes
 No
 Unknown

Calcium channel blockers Yes
 No
 Unknown

Digoxin Yes
 No
 Unknown

Hydralazine Yes
 No
 Unknown

Loop diuretics Yes
 No
 Unknown

If yes, enter dosage: mg/day

ST= Unknown

Type of Loop Diuretic: Furosemide
 Torsemide
 Bumetanide
 Other

**Low molecular weight heparin
(Lovenox, Fragmin, Innohep)** Yes
 No
 Unknown

Nitric oxide Yes
 No
 Unknown

Sildenafil/ Bosentan Yes
 No
 Unknown

UFH: Unfractionated Heparin Yes
 No
 Unknown

Warfarin (coumadin) Yes
 No
 Unknown

Arixtra (fondaparinux) Yes
 No
 Unknown

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

Transfusion

Was there a Tranfusion? Yes
 No
 Unknown

**If yes, enter number of PRBC (Total
number of cc's received)**

ST= Unknown

1 Month Followup - Pedimacs

Laboratory

Sodium

mEq/L

mmol/L

ST= Unknown
 Not done

Potassium

mEq/L

mmol/L

ST= Unknown
 Not done

Blood urea nitrogen

mg/dL

mmol/L

ST= Unknown
 Not done

Creatinine

mg/dL

umol/L

ST= Unknown
 Not done

SGPT/ALT (alanine aminotransferase/ALT)

u/L

ST= Unknown
 Not done

SGOT/AST (aspartate aminotransferase/AST)

u/L

ST= Unknown
 Not done

LDH

units/L, U/L, ukat/L

ST= Unknown
 Not done

Total bilirubin

mg/dL

umol/L

ST= Unknown
 Not done

Bilirubin direct

mg/dL

umol/L

ST= Unknown
 Not Done

Bilirubin indirect mg/dL
 umol/L
ST= Unknown
 Not Done

Albumin g/dL
 g/L
ST= Unknown
 Not done

Pre-albumin mg/dL
 mg/L
ST= Unknown
 Not done

Total Cholesterol mg/dL
 mmol/L
ST= < 50 mg/dL
 Unknown
 Not done

Brain natriuretic peptide BNP pg/ml
 ng/L
ST= > 7500 pg/mL
 Unknown
 Not done

NT pro brain natriuretic peptide Pro-BNP pg/ml
 ng/L
ST= Unknown
 Not done

White blood cell count x10³/uL
 x10⁹/uL
ST= Unknown
 Not done

Reticulocyte count %
ST= Unknown
 Not Done

Hemoglobin g/dL
 g/L
 mmol/L
ST= Unknown
 Not done

Hemoglobin A1C % mmol/mol**Estimated Average Glucose (eAG):** mg/dL mmol/LST= Unknown Not Done**Platelets** x10³/uL x10⁹/uLST= Unknown Not done**INR** international unitsST= Unknown Not done**Plasma-free hemoglobin** mg/dL g/LST= Unknown Not Done**Positive antiheparin/platelet antibody (HIT)** Yes No Unknown**If Yes, are they on direct thrombin inhibitors** Yes No Unknown**If Yes, Enter Drugs:** Aspirin Dipyridamole Plavix Heparin Coumadin Direct thrombin inhibitors (ex: arg, lip, val...)**Was a TEG done?** Yes No Unknown**ThrombElastoGraph Hemostasis System (TEG) profile, MA k** max amplitude in kaolinST= Unknown Not Done**ThrombElastoGraph Hemostasis System (TEG) profile, R k** reaction time in kaolinST= Unknown Not Done

**ThrombElastoGraph
HemostasisSystem (TEG) profile, R
h**

reaction time w/heparinase

- ST= Unknown
 Not Done

CRP or hs-CRP

mg/dL

- ST= Unknown
 Not done

Lupus Anticoagulant

- Positive
 Negative
 Unknown

1 Week Followup - Pedimacs

Followup Status (1 Week Followup (+/- 3 days))

Select one of the following

- Inpatient
- Outpatient
- Other Facility
- Unable to obtain follow-up information

Follow-up date

Facility Type

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

State 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

Was patient intubated?

- Yes
- No
- Unknown

Was patient on dialysis?

- Yes
- No
- Unknown

Pump Change

Pump Exchange

- Yes
- No
- Unknown

If yes, please select one of the following:
Please select appropriate reason:

- Intracorporeal device
- Para- or Extra- corporeal device
- Upsizing device because of patient growth status
- All other reasons would categorize the pump change as a Device Malfunction
- Thrombus NOT associated with hemolysis
- Change in hemodynamics
- Clinical status
- Device parameters

Was there a Console Change?

- Yes
- No
- Unknown

Date of console change

ST= Unknown

Original Console Name

New Console Name

Medical Condition**NYHA Class**

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

Ross Classification of Congestive Heart Failure

- Ross Class I: No limitations or symptoms.
- Ross Class II: No growth failure.
- Ross Class III: Growth failure.
- Ross Class IV: Symptomatic at rest.
- Not applicable: ≥ 2 years of age
- Unknown

Choose all indicated symptoms that apply.

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

Choose all indicated symptoms that apply.

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

Choose all indicated symptoms that apply.

- Tachypnea
- Retractions
- Grunting
- Diaphoresis
- Unknown

Functional Capacity**Sedated**

- Yes
- No
- Unknown

Paralyzed

- Yes
- No
- Unknown

Intubated

- Yes
- No
- Unknown

Ambulating

Yes
 No
 Unknown

Primary Nutrition

Orally
 Per feeding tube
 TPN
 Not Applicable

Excursions

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

Yes
 No
 Unknown
 Not Applicable

If yes, where (please select all that apply)

Playroom
 Cafeteria
 Walk outside
 Sitting room
 General rehab
 None

ZONES

Hemolysis Zone

Please enter the peak Plasma-free hemoglobin (PFH) since Post-Op Day 4:

ST= Unknown
 Not Done

What is your hospital's upper limit of the normal range of peak PFH?

ST= Unknown
 Not Done

Please enter the peak serum lactate dehydrogenase (LDH) since Post-Op Day 4:

ST= Unknown
 Not Done

What is your hospital's upper limit of the normal range of LDH?

ST= Unknown
 Not Done

Enter the Maximum and Minimum HCT or HGB since the Post-Op Day 4.

Min. HCT:

ST= Unknown
 Not Done

Max. HCT:

ST= Unknown
 Not Done

Min. HGB:

ST= Unknown
 Not Done

Max. HGB:

ST= Unknown
 Not Done

Highest Total Bilirubin since Post-Op Day 4:

ST= Unknown
 Not Done

**Has the following been present at any time since Post-Op Day 4?
 Physical Findings (select all that apply):**

Hemoglobinuria (Tea-Colored Urine)? Yes
 No
 Unknown

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

Right Heart Failure Zone

Clinical Findings – Since the last visit.

CVP or RAP > 16 mmHg? Yes
 No
 Unknown
 Not Done

Dilated Vena Cava with absence of Inspiratory Variation by Echo? Yes
 No
 Unknown
 Not Done

Clinical findings of elevated jugular venous distension at least half way up the neck in an upright patient? Yes
 No
 Unknown

Peripheral Edema? Yes
 No
 Unknown

Ascites? Yes
 No
 Unknown

Has the patient been on Inotropes since the last visit?

- Yes
 No
 Unknown

If yes, select all that apply:

- Dopamine
 Dobutamine
 Milrinone
 Isoproterenol
 Epinephrine
 Norepinephrine
 Levosimendan
 Unknown
 Vasopressin
 Nitroprusside
 Fenoldopam
 Prostacyclin

Nesiritide?

- Yes
 No
 Unknown

Has the patient had a RVAD implant since the last visit?

- Yes
 No
 Unknown

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

- Yes
 No
 Unknown

If yes, please enter the Modified Rankin Scale.

Modified Rankin Scale

- 0 – No symptoms at all
 1 - No Significant disability: despite symptoms: able to carry out all usual duties and activities
 2 - Slight disability: unable to carry out all previous activities but able to look after own affairs without assistance
 3 - Moderate disability: requiring some help, but able to walk without assistance.
 4 - Moderately severe disability: unable to walk without assistance, and unable to attend to own bodily needs without assistance.
 5 - Severe disability: bedridden, incontinent and requiring constant nursing care and attention.
 6 - Dead

ST= Not Documented
 Not Done

1 Week Followup - Pedimacs

Hemodynamics

General Hemodynamics

Systolic blood pressure mmHg

ST= Unknown
 Not done

Diastolic blood pressure mmHg

ST= Unknown
 Not done

Mean Arterial Blood Pressure (MAP) mmHg

ST= Unknown
 Not done

ECG rhythm

- Sinus
 Atrial fibrillation
 Atrial Flutter
 Paced: Atrial pacing
 Paced: Ventricular pacing
 Paced: Atrial and ventricular pacing
 Unknown
 Not done
 Other, specify

Height in

cm

ST= Unknown
 Not done

Weight lbs

kg

ST= Unknown
 Not done

Invasive Hemodynamics

Date of Measurement

ST= Unknown
 Not Done

Pulmonary artery systolic pressure mmHg

ST= Unknown
 Not Done

Pulmonary artery diastolic pressure

 mmHg

ST= Unknown
 Not Done

Mean RA Pressure

 mmHg

ST= Unknown
 Not Done

PVR

 wood units

ST= Unknown
 Not Done

Mean Pulmonary artery wedge pressure

 mmHg

ST= Unknown
 Not Done

Central venous pressure (CVP)

 mmHg

ST= Unknown
 Not Done

Cardiac Index

 L/min/M² (by Swan)

ST= Unknown
 Not Done

Was Cardiac Index Measured by Fick or Thermodilution?

- Yes
- No
- Unknown

Choose Method

- Fick
- Thermodilution

1 Week Followup - Pedimacs

Medications

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

ACE inhibitors Yes
 No
 Unknown

Aldosterone antagonist Yes
 No
 Unknown

Amiodarone Yes
 No
 Unknown

Angiotensin receptor blocker drug Yes
 No
 Unknown

Antiplatelet therapy drug Yes
 No
 Unknown

Select drug(s) Aspirin
 Dextran
 Dipyridamole
 Clopidogrel
 Ticlopidine
 Unknown
 Other, specify

Thrombolytic Yes
 No
 Unknown

Beta-blockers Yes
 No
 Unknown

Calcium channel blockers Yes
 No
 Unknown

Digoxin Yes
 No
 Unknown

Hydralazine Yes
 No
 Unknown

Loop diuretics Yes
 No
 Unknown

**Low molecular weight heparin
(Lovenox, Fragmin, Innohep)** Yes
 No
 Unknown

Nitric oxide Yes
 No
 Unknown

Sildenafil/ Bosentan Yes
 No
 Unknown

UFH: Unfractionated Heparin Yes
 No
 Unknown

Warfarin (coumadin) Yes
 No
 Unknown

Arixtra (fondaparinux) Yes
 No
 Unknown

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

Transfusion

Was there a Tranfusion? Yes
 No
 Unknown

**If yes, enter number of PRBC (Total
number of cc's received)**

cc

ST= Unknown

1 Week Followup - Pedimacs

Laboratory

Sodium

mEq/L

mmol/L

ST= Unknown
 Not done

Potassium

mEq/L

mmol/L

ST= Unknown
 Not done

Blood urea nitrogen

mg/dL

mmol/L

ST= Unknown
 Not done

Creatinine

mg/dL

umol/L

ST= Unknown
 Not done

SGPT/ALT (alanine aminotransferase/ALT)

u/L

ST= Unknown
 Not done

SGOT/AST (aspartate aminotransferase/AST)

u/L

ST= Unknown
 Not done

LDH

units/L, U/L, ukat/L

ST= Unknown
 Not done

Total bilirubin

mg/dL

umol/L

ST= Unknown
 Not done

Bilirubin direct

mg/dL

umol/L

ST= Unknown
 Not Done

Bilirubin indirect mg/dL
 umol/LST= Unknown
 Not Done**Albumin** g/dL
 g/LST= Unknown
 Not done**Pre-albumin** mg/dL
 mg/LST= Unknown
 Not done**Total Cholesterol** mg/dL
 mmol/LST= < 50 mg/dL
 Unknown
 Not done**Brain natriuretic peptide BNP** pg/ml
 ng/LST= > 7500 pg/mL
 Unknown
 Not done**NT pro brain natriuretic peptide Pro-BNP** pg/ml
 ng/LST= Unknown
 Not done**White blood cell count** x10³/uL
 x10⁹/uLST= Unknown
 Not done**Reticulocyte count** %ST= Unknown
 Not Done**Hemoglobin** g/dL
 g/L
 mmol/LST= Unknown
 Not done

Hemoglobin A1C % mmol/mol**Estimated Average Glucose (eAG):** mg/dL mmol/LST= Unknown Not Done**Platelets** x10³/uL x10⁹/uLST= Unknown Not done**INR** international unitsST= Unknown Not done**Plasma-free hemoglobin** mg/dL g/LST= Unknown Not Done**Positive antiheparin/platelet antibody (HIT)** Yes No Unknown**If Yes, are they on direct thrombin inhibitors** Yes No Unknown**If Yes, Enter Drugs:** Aspirin Dipyridamole Plavix Heparin Coumadin Direct thrombin inhibitors (ex: arg, lip, val...)**Was a TEG done?** Yes No Unknown**ThrombElastoGraph Hemostasis System (TEG) profile, MA k** max amplitude in kaolinST= Unknown Not Done**ThrombElastoGraph Hemostasis System (TEG) profile, R k** reaction time in kaolinST= Unknown Not Done

**ThrombElastoGraph
HemostasisSystem (TEG) profile, R
h**

reaction time w/heparinase

- ST= Unknown
 Not Done

CRP or hs-CRP

mg/dL

- ST= Unknown
 Not done

Lupus Anticoagulant

- Positive
 Negative
 Unknown



1 Year Post Cessation of Mechanical Support - Pedimacs

Enter Information you are reporting

Date of Event

Death

Is the patient deceased ?

- Yes
 No

Death Date

Primary cause of death

- Respiratory: Venous Thromboembolism Event
- Respiratory: Respiratory Failure
- Respiratory: Pulmonary: Other, specify
- Circulatory: Arterial Non-CNS Thromboembolism
- Circulatory: Myocardial Infarction
- Circulatory: Myocardial Rupture
- Circulatory: Ruptured Aortic aneurysm
- Circulatory: Right Heart Failure
- Circulatory: Major Bleeding
- Circulatory: Cardiac Arrhythmia
- Circulatory: Hemolysis
- Circulatory: Hypertension
- Circulatory: Other, Specify
- Circulatory: Sudden unexplained death
- Circulatory: CHF
- Circulatory: Heart Disease
- Circulatory: End Stage Cardiomyopathy
- Circulatory: End Stage Ischemic Cardiomyopathy
- Circulatory: Pericardial Fluid Collection (effusion)
- Digestive (Intestinal or GI/GU): Hepatic Dysfunction
- Digestive (Intestinal or GI/GU): Renal Dysfunction
- Digestive (Intestinal or GI/GU): GI Disorder
- Digestive (Intestinal or GI/GU): Fluid/Electrolyte Disorder
- Digestive (Intestinal or GI/GU): Pancreatitis
- Nervous System: Neurological Dysfunction
- Psychiatric Episode/Suicide
- Major Infection
- Device Malfunction
- Multiple System Organ Failure (MSOF)
- Withdrawal of Support, specify
- Cancer
- Wound Dehiscence
- Trauma/accident, specify
- Endocrine
- Hematological
- Other, specify

Cancer

- CNS
- GI
- Lymph
- ENT
- Pulmonary
- Renal
- Breast
- Reproductive
- Skin
- Other
- Unknown

Specify support withdrawn

Specify

Transplant

Was the patient transplanted ?

- Yes
- No

Transplant date

3 Month Followup - Pedimacs

Followup Status (3 Month Followup (+/- 1 month))

Select one of the following

- Inpatient
- Outpatient
- Other Facility
- Unable to obtain follow-up information

Follow-up date

Facility Type

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

State 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

Was patient intubated?

- Yes
- No
- Unknown

Was patient on dialysis?

- Yes
- No
- Unknown

Current Device Strategy

- Bridge to Recovery
- Rescue Therapy
- Bridge to Transplant (patient currently listed for transplant)
- Possible Bridge to Transplant - Likely to be eligible
- Possible Bridge to Transplant - Moderate likelihood of becoming eligible
- Possible Bridge to Transplant - Unlikely to become eligible
- Destination Therapy

List Date for Transplant

ST= Unknown

Pump Change

Pump Exchange

- Yes
- No
- Unknown

If yes, please select one of the following:

- Intracorporeal device
- Para- or Extra- corporeal device
- Upsizing device because of patient growth status
- All other reasons would categorize the pump change as a Device Malfunction

Please select appropriate reason:

- Thrombus NOT associated with hemolysis
- Change in hemodynamics
- Clinical status
- Device parameters

Was there a Console Change?

- Yes
- No
- Unknown

Date of console change

ST= Unknown

Original Console Name

New Console Name

Functional Capacity

Sedated

- Yes
- No
- Unknown

Paralyzed

- Yes
- No
- Unknown

Intubated

- Yes
- No
- Unknown

Ambulating

- Yes
- No
- Unknown

Primary Nutrition

- Orally
- Per feeding tube
- TPN
- Not Applicable

Excursions

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

- Yes
- No
- Unknown
- Not Applicable

If yes, where (please select all that apply)

- Playroom
- Cafeteria
- Walk outside
- Sitting room
- General rehab
- None

ZONES

Hemolysis Zone

Please enter the peak Plasma-free hemoglobin (PFH) since the last follow-up visit:

ST= Unknown
 Not Done

What is your hospital's upper limit of the normal range of peak PFH:

ST= Unknown
 Not Done

Please enter the peak serum lactate dehydrogenase (LDH) since the last follow-up visit:

ST= Unknown
 Not Done

What is your hospital's upper limit of the normal range of LDH:

ST= Unknown
 Not Done

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

Min. HCT:

ST= Unknown
 Not Done

Max. HCT:

ST= Unknown
 Not Done

Min. HGB:

ST= Unknown
 Not Done

Max. HGB:

ST= Unknown
 Not Done

Highest Total Bilirubin since the last Follow-up period:

ST= Unknown
 Not Done

Has the following been present at any time since the last Follow-up period? Physical Findings (select all that apply):

Hemoglobinuria (Tea-Colored Urine)?

Yes
 No
 Unknown

Pump malfunction and/or abnormal pump parameters?

Yes
 No
 Unknown

Right Heart Failure Zone

Clinical Findings – Since the last followup.

CVP or RAP > 16 mmHg?

Yes
 No
 Unknown
 Not Done

Dilated Vena Cava with absence of Inspiratory Variation by Echo?

Yes
 No
 Unknown
 Not Done

Clinical findings of elevated jugular venous distension at least half way up the neck in an upright patient?

Yes
 No
 Unknown

Peripheral Edema?

Yes
 No
 Unknown

Ascites?

Yes
 No
 Unknown

Has the patient been on Inotropes since the last Follow-up?

Yes
 No
 Unknown

If yes, select all that apply:

Dopamine
 Dobutamine
 Milrinone
 Isoproterenol
 Epinephrine
 Norepinephrine
 Levosimendan
 Unknown
 Vasopressin
 Nitroprusside
 Fenoldopam
 Prostacyclin

Nesiritide?

Yes
 No
 Unknown

Has the patient had a RVAD implant since the last Follow-up or rehospitalization?

Yes
 No
 Unknown

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

Yes
 No
 Unknown

If yes, please enter the Modified Rankin Scale.

Modified Rankin Scale

- 0 – No symptoms at all
- 1 - No Significant disability: despite symptoms: able to carry out all usual duties and activities
- 2 - Slight disability: unable to carry out all previous activities but able to look after own affairs without assistance
- 3 - Moderate disability: requiring some help, but able to walk without assistance.
- 4 - Moderately severe disability: unable to walk without assistance, and unable to attend to own bodily needs without assistance.
- 5 - Severe disability: bedridden, incontinent and requiring constant nursing care and attention.
- 6 - Dead

ST= Not Documented
 Not Done

3 Month Followup - Pedimacs

Hemodynamics

General Hemodynamics

Systolic blood pressure mmHg

ST= Unknown
 Not done

Diastolic blood pressure mmHg

ST= Unknown
 Not done

Mean Arterial Blood Pressure (MAP) mmHg

ST= Unknown
 Not done

ECG rhythm

- Sinus
 Atrial fibrillation
 Atrial Flutter
 Paced: Atrial pacing
 Paced: Ventricular pacing
 Paced: Atrial and ventricular pacing
 Unknown
 Not done
 Other, specify

Height in

cm

ST= Unknown
 Not done

Weight lbs

kg

ST= Unknown
 Not done

Invasive Hemodynamics

Pulmonary artery systolic pressure mmHg

ST= Unknown
 Not Done

Pulmonary artery diastolic pressure mmHg

ST= Unknown

Not Done

Mean RA Pressure

mmHg

ST= Unknown

Not Done

PVR

wood units

ST= Unknown

Not Done

Mean Pulmonary artery wedge pressure

mmHg

ST= Unknown

Not Done

Central venous pressure (CVP)

mmHg

ST= Unknown

Not Done

Cardiac Index

L/min/M² (by Swan)

ST= Unknown

Not Done

Was Cardiac Index Measured by Fick or Thermodilution?

Yes

No

Unknown

Choose Method

Fick

Thermodilution

3 Month Followup - Pedimacs

Medications

Was the patient sent home with an IV?

Yes
 No
 Unknown

ACE inhibitors

Yes
 No
 Unknown

Aldosterone antagonist

Yes
 No
 Unknown

Amiodarone

Yes
 No
 Unknown

Angiotensin receptor blocker drug

Yes
 No
 Unknown

Antiplatelet therapy drug

Yes
 No
 Unknown

Select drug(s)

Aspirin
 Dextran
 Dipyridamole
 Clopidogrel
 Ticlopidine
 Unknown
 Other, specify

Thrombolytic

Yes
 No
 Unknown

Beta-blockers

Yes
 No
 Unknown

Digoxin

Yes
 No
 Unknown

Loop diuretics

- Yes
 No
 Unknown

If yes, enter dosage:

mg/day

ST= Unknown

Type of Loop Diuretic:

- Furosemide
 Torsemide
 Bumetanide
 Other

**Low molecular weight heparin
(Lovenox, Fragmin, Innohep)**

- Yes
 No
 Unknown

Nitric oxide

- Yes
 No
 Unknown

Sildenafil/ Bosentan

- Yes
 No
 Unknown

UFH: Unfractionated Heparin

- Yes
 No
 Unknown

Warfarin (coumadin)

- Yes
 No
 Unknown

Arixtra (fondaparinux)

- Yes
 No
 Unknown

**Did patient receive new IV or oral
medication to treat hypertension?**

- Yes
 No
 Unknown

Transfusion

Was there a Tranfusion?

- Yes
 No
 Unknown

**If yes, enter number of PRBC (Total
number of cc's received)**

ST= Unknown

3 Month Followup - Pedimacs

Laboratory

Sodium mEq/L
 mmol/L
 ST= Unknown
 Not done

Potassium mEq/L
 mmol/L
 ST= Unknown
 Not done

Blood urea nitrogen mg/dL
 mmol/L
 ST= Unknown
 Not done

Creatinine mg/dL
 umol/L
 ST= Unknown
 Not done

SGPT/ALT (alanine aminotransferase/ALT) u/L
 ST= Unknown
 Not done

SGOT/AST (aspartate aminotransferase/AST) u/L
 ST= Unknown
 Not done

LDH units/L, U/L, ukat/L
 ST= Unknown
 Not done

Total bilirubin mg/dL
 umol/L
 ST= Unknown
 Not done

Bilirubin direct mg/dL
 umol/L
 ST= Unknown
 Not Done

Bilirubin indirect

mg/dL
 umol/L

ST= Unknown
 Not Done

Albumin

g/dL
 g/L

ST= Unknown
 Not done

Pre-albumin

mg/dL
 mg/L

ST= Unknown
 Not done

Total Cholesterol

mg/dL
 mmol/L

ST= < 50 mg/dL
 Unknown
 Not done

Brain natriuretic peptide BNP

pg/ml
 ng/L

ST= > 7500 pg/mL
 Unknown
 Not done

NT pro brain natriuretic peptide Pro-BNP

pg/ml
 ng/L

ST= Unknown
 Not done

White blood cell count

x10³/uL
 x10⁹/uL

ST= Unknown
 Not done

Reticulocyte count

%

ST= Unknown
 Not Done

Hemoglobin

g/dL
 g/L
 mmol/L

ST= Unknown
 Not done

Hemoglobin A1C % mmol/mol**Estimated Average Glucose (eAG):** mg/dL mmol/LST= Unknown Not Done**Platelets** x10³/uL x10⁹/uLST= Unknown Not done**INR** international unitsST= Unknown Not done**Plasma-free hemoglobin** mg/dL g/LST= Unknown Not Done**Positive antiheparin/platelet antibody (HIT)** Yes No Unknown**If Yes, are they on direct thrombin inhibitors** Yes No Unknown**If Yes, Enter Drugs:** Aspirin Dipyridamole Plavix Heparin Coumadin Direct thrombin inhibitors (ex: arg, lip, val...)**Was a TEG done?** Yes No Unknown**ThrombElastoGraph Hemostasis System (TEG) profile, MA k** max amplitude in kaolinST= Unknown Not Done**ThrombElastoGraph Hemostasis System (TEG) profile, R k** reaction time in kaolinST= Unknown Not Done

**ThrombElastoGraph
HemostasisSystem (TEG) profile, R
h**

reaction time w/heparinase

- ST= Unknown
 Not Done

Sensitivity CRP

mg/L

- ST= Unknown
 Not done

Lupus Anticoagulant

- Positive
 Negative
 Unknown

3 Month Followup - Pedimacs

Device Flow Chart

Device Function

Left Flow LPM
ST= Unknown

Right Flow LPM
ST= Unknown
 Not Applicable

Left Fill Volume: ml
ST= Unknown

Right Fill Volume ml
ST= Unknown
 Not Applicable

Device Parameters

Pump Rate BPM
ST= Unknown

Vacuum Pressure mm Hg
ST= Unknown
 Not Applicable

Left Drive Pressure mm Hg
ST= Unknown
 Not Applicable

Right Drive Pressure mm Hg
ST= Unknown
 Not Applicable

Device Inspection

Auscultation Abnormal
 Normal
 Not Applicable

3 Month Followup - Pedimacs

Device Flow Chart

Device Function

Pump Flow LPM
ST= Unknown

Pulsality Index
ST= Unknown

Pump Power Watts
ST= Unknown

Device Parameters

Pump Speed RPM
ST= Unknown

Low Speed RPM
ST= Unknown

Device Inspection

Auscultation Abnormal
 Normal
 Not Applicable

Driveline Abnormal
 Normal
 Not Applicable

3 Month Followup - Pedimacs

Device Flow Chart

Device Function

Pump Flow LPM
ST= Unknown

Pump Power Watts
ST= Unknown

Device Parameters

Pump Speed RPM
ST= Unknown

Device Inspection

Auscultation Abnormal
 Normal
 Not Applicable

Driveline Abnormal
 Normal
 Not Applicable

3 Month Followup - Pedimacs

Device Flow Chart

Device Function

Pump Flow LPM
ST= Unknown

Device Parameters

Control Mode
 Synchronous
 Asynchronous
 Independent
 Not Applicable

Pump Rate BPM
ST= Unknown

Device Inspection

Depositions
 Yes
 No
 Not Applicable

Depositions Description

Full Ejection
 Yes
 No
 Not Applicable

Systolic Pressure: mm Hg
ST= Unknown

Diastolic Pressure: mm Hg
ST= Unknown

Percent Systole: %
ST= Unknown

Device Function (RVAD)

Pump Flow (RVAD) LPM
ST= Unknown

Device Parameters (RVAD)

Control Mode (RVAD) Both
 Synchronous
 Asynchronous
 Independent
 Not Applicable

Pump Rate (RVAD) BPM
ST= Unknown

Device Inspection (RVAD)

Depositions (RVAD) Yes

- No
- Not Applicable

Depositions Description (RVAD)

Full Ejection (RVAD)

- Yes
- No
- Not Applicable

Systolic Pressure (RVAD):

mm Hg

ST= Unknown

Diastolic Pressure (RVAD):

mm Hg

ST= Unknown

Percent Systole (RVAD):

%

ST= Unknown

3 Month Followup - Pedimacs

Device Flow Chart

Device Function

Pump Flow LPM
ST= Unknown

Pump Power Watts
ST= Unknown

Device Parameters

Pump Speed RPM
ST= Unknown

Device Inspection

Auscultation Abnormal
 Normal
 Not Applicable

Driveline Abnormal
 Normal
 Not Applicable

Device Funtion (RVAD)

Pump Flow (RVAD) LPM
ST= Unknown

Device Parameters (RVAD)

Pump Speed (RVAD) RPM
ST= Unknown

Device Inspection (RVAD)

Depositions AbNormal
 Normal
 Not Applicable

3 Month Followup - Pedimacs

Exercise Function

All patients ≥ 10 years of age at time of implant should attempt to complete these functional capacity measurements especially for those patients classified as Intermacs patient profile level 4-7

6 minute walk feet

- ST= Not done
 Not done: too sick
 Not done: other
 Not done: age inappropriate

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

Gait Speed (1st 15 foot walk) seconds

- ST= Not done
 Not done: too sick
 Not done: other
 Not done: age inappropriate

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

Peak VO2 Max mL/kg/min

- ST= Not done
 Not done: too sick
 Not done: other
 Not done: age inappropriate

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

R Value at peak %

- ST= Not done
 Not done: too sick
 Not done: other
 Not done: age inappropriate

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

Medical Condition

- NYHA Class**
- Class I: No limitation of physical activity; physical activity does not cause fatigue, palpitation or shortness of breath.
 - Class II: Slight limitation of physical activity; comfortable at rest, but ordinary physical activity results in fatigue, palpitations or shortness of

breath.

- Class III: Marked limitation of physical activity; comfortable at rest, but less than ordinary activity causes fatigue, palpitation or shortness of breath.
- Class IV: Unable to carry on minimal physical activity without discomfort; symptoms may be present at rest.
- Unknown

Ross Classification of Congestive Heart Failure

- Ross Class I: No limitations or symptoms.
- Ross Class II: No growth failure.
- Ross Class III: Growth failure.
- Ross Class IV: Symptomatic at rest.
- Not applicable: ≥ 2 years of age
- Unknown

Choose all indicated symptoms that apply.

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

Choose all indicated symptoms that apply.

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

Choose all indicated symptoms that apply.

- Tachypnea
- Retractions
- Grunting
- Diaphoresis
- Unknown

3 Month Followup - Pedimacs

Quality Of Life

(QOL surveys cannot be administered after the visit date)

PedsQL

- Did the child complete a form?**
- Yes
 - No
 - Unknown

- Please select the 'Child' form:**
- PedsQL Young Child (5-7 yrs)
 - PedsQL Child (8-12 yrs)
 - PedsQL Teen (13-18 yrs)

PHYSICAL FUNCTIONING (problems with...)

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

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

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

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

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

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

- Do you have hurts or aches:**
- 0 - Not at all
 - 2 - Sometimes
 - 4 - A lot
 - Unknown or Not Documented

Where?

Do you ever feel too tired to play:

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

EMOTIONAL FUNCTIONING (problems with...)**Do you feel scared:**

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

Do you feel sad:

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

Do you feel mad:

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

Do you have trouble sleeping:

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

Do you worry about what will happen to you:

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

SOCIAL FUNCTIONING (problems with...)**Is it hard for you to get along with other kids:**

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

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

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

Do other kids tease you:

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

Can other kids do things that you cannot do:

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

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

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

SCHOOL FUNCTIONING (problems with...)

Is it hard for you to pay attention in class:

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

Do you forget things:

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

Is it hard to keep up with schoolwork:

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

Do you miss school because of not feeling good:

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

Do you miss school because you have to go to the doctor's or hospital:

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

If No, Please select a reason why the PedsQOL was not completed:

- Too sick
- Administrative

If Administrative: Select a specific reason:

- Urgent implant, no time
- Coordinator too busy or forgot
- Unable to contact patient
- Other reason (specify)

VADQoL

Did the child complete a form?

- Yes
- No
- Unknown

The VAD noise bothers me when I am awake:

- Always
- Very Often
- Sometimes
- Rarely
- Never

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

- Always
- Very Often
- Sometimes
- Rarely
- Never

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

- Always
- Very Often
- Sometimes
- Rarely
- Never

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

- Always
- Very Often
- Sometimes
- Rarely
- Never

I am bothered by how I look with the VAD:

- Always
- Very Often
- Sometimes
- Rarely
- Never

I worry about the VAD breaking or malfunctioning:

- Always
- Very Often
- Sometimes
- Rarely
- Never

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

- Always
- Very Often
- Sometimes
- Rarely
- Never

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

- Always
- Very Often
- Sometimes
- Rarely
- Never

I cannot participate in usual play activities with the VAD:

- Always
- Very Often
- Sometimes
- Rarely
- Never

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

- Always
- Very Often
- Sometimes
- Rarely
- Never

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

- High
- Between High and Medium
- Medium
- Between Low and Medium
- Low

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

- High
- Between High and Medium
- Medium
- Between Low and Medium
- Low

If No, Please select a reason why the VADQoL form was not completed:

- Too sick
- Administrative

If Administrative: Select a specific reason:

- Urgent implant, no time
- Coordinator too busy or forgot
- Unable to contact patient
- Other reason (specify)

3 Month Followup

Quality Of Life

(QOL surveys cannot be administered after the visit date)

PedsQL

- Did the child complete a form?**
- Yes
 - No
 - Unknown

- Please select the 'Child' form:**
- PedsQL Young Child (5-7 yrs)
 - PedsQL Child (8-12 yrs)
 - PedsQL Teen (13-18 yrs)

ABOUT MY HEALTH AND ACTIVITIES (problems with...)

- It is hard for me to walk more than one block:**
- 0 - Never a problem
 - 1 - Almost never a problem
 - 2 - Sometimes a problem
 - 3 - Often a problem
 - 4 - Almost always a problem
 - Unknown or Not Documented

- It is hard for me to run:**
- 0 - Never a problem
 - 1 - Almost never a problem
 - 2 - Sometimes a problem
 - 3 - Often a problem
 - 4 - Almost always a problem
 - Unknown or Not Documented

- It is hard for me to do sports activity or exercise:**
- 0 - Never a problem
 - 1 - Almost never a problem
 - 2 - Sometimes a problem
 - 3 - Often a problem
 - 4 - Almost always a problem
 - Unknown or Not Documented

- It is hard for me to lift something heavy:**
- 0 - Never a problem
 - 1 - Almost never a problem
 - 2 - Sometimes a problem
 - 3 - Often a problem
 - 4 - Almost always a problem
 - Unknown or Not Documented

- It is hard for me to take a bath or shower by myself:**
- 0 - Never a problem
 - 1 - Almost never a problem
 - 2 - Sometimes a problem
 - 3 - Often a problem
 - 4 - Almost always a problem
 - Unknown or Not Documented

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

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

I hurt or ache:

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

Where?

I have low energy:

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

ABOUT MY FEELINGS (problems with...)

I feel afraid or scared:

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

I feel sad or blue:

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

I feel angry:

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

I have trouble sleeping:

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

I worry about what will happen to me:

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

HOW I GET ALONG WITH OTHERS (problems with...)

I have trouble getting along with other kids:

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

Other kids do not want to be my friend:

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

Other kids tease me:

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

I cannot do things other kids my age can do:

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

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

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

ABOUT SCHOOL (problems with...)

Is it hard to pay attention in class:

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

I forget things:

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

I have trouble keeping up with my schoolwork:

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

I miss school because of not feeling well:

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

I miss school to go to the doctor or hospital:

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

If No, Please select a reason why the PedsQOL was not completed:

- Too sick
- Administrative

If Administrative: Select a specific reason:

- Urgent implant, no time
- Coordinator too busy or forgot
- Unable to contact patient
- Other reason (specify)

VADQoL

Did the child complete a form?

- Yes
- No
- Unknown

The VAD noise bothers me when I am awake:

- Always
- Very Often
- Sometimes
- Rarely
- Never

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

- Always
- Very Often

- Sometimes
- Rarely
- Never

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

- Always
- Very Often
- Sometimes
- Rarely
- Never

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

- Always
- Very Often
- Sometimes
- Rarely
- Never

I am bothered by how I look with the VAD:

- Always
- Very Often
- Sometimes
- Rarely
- Never

I worry about the VAD breaking or malfunctioning:

- Always
- Very Often
- Sometimes
- Rarely
- Never

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

- Always
- Very Often
- Sometimes
- Rarely
- Never

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

- Always
- Very Often
- Sometimes
- Rarely
- Never

I cannot participate in usual play activities with the VAD:

- Always
- Very Often
- Sometimes

- Rarely
- Never

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

- Always
- Very Often
- Sometimes
- Rarely
- Never

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

- High
- Between High and Medium
- Medium
- Between Low and Medium
- Low

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

- High
- Between High and Medium
- Medium
- Between Low and Medium
- Low

If No, Please select a reason why the VADQoL form was not completed:

- Too sick
- Administrative

If Administrative: Select a specific reason:

- Urgent implant, no time
- Coordinator too busy or forgot
- Unable to contact patient
- Other reason (specify)

3 Month Followup

Quality Of Life

(QOL surveys cannot be administered after the visit date)

PedsQL

- Did the child complete a form?**
- Yes
 - No
 - Unknown

- Please select the 'Child' form:**
- PedsQL Young Child (5-7 yrs)
 - PedsQL Child (8-12 yrs)
 - PedsQL Teen (13-18 yrs)

ABOUT MY HEALTH AND ACTIVITIES (problems with...)

- It is hard for me to walk more than one block:**
- 0 - Never a problem
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 - 3 - Often a problem
 - 4 - Almost always a problem
 - Unknown or Not Documented

- It is hard for me to run:**
- 0 - Never a problem
 - 1 - Almost never a problem
 - 2 - Sometimes a problem
 - 3 - Often a problem
 - 4 - Almost always a problem
 - Unknown or Not Documented

- It is hard for me to do sports activity or exercise:**
- 0 - Never a problem
 - 1 - Almost never a problem
 - 2 - Sometimes a problem
 - 3 - Often a problem
 - 4 - Almost always a problem
 - Unknown or Not Documented

- It is hard for me to lift something heavy:**
- 0 - Never a problem
 - 1 - Almost never a problem
 - 2 - Sometimes a problem
 - 3 - Often a problem
 - 4 - Almost always a problem
 - Unknown or Not Documented

- It is hard for me to take a bath or shower by myself:**
- 0 - Never a problem
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 - 4 - Almost always a problem
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around the house:**

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- 4 - Almost always a problem
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- Unknown or Not Documented

Where?

I have low energy:

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

ABOUT MY FEELINGS (problems with...)

I feel afraid or scared:

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

I feel sad or blue:

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

I feel angry:

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

I have trouble sleeping:

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

I worry about what will happen to me:

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

HOW I GET ALONG WITH OTHERS (problems with...)

I have trouble getting along with other teens:

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

Other teens do not want to be my friend:

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

Other teens tease me:

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

I cannot do things other teens my age can do:

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

It is hard to keep up with peers:

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

ABOUT SCHOOL (problems with...)

Is it hard to pay attention in class:

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

I forget things:

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

I have trouble keeping up with my schoolwork:

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

I miss school because of not feeling well:

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

I miss school to go to the doctor or hospital:

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

If No, Please select a reason why the PedsQOL was not completed:

- Too sick
- Administrative

If Administrative: Select a specific reason:

- Urgent implant, no time
- Coordinator too busy or forgot
- Unable to contact patient
- Other reason (specify)

VADQoL

Did the child complete a form?

- Yes
- No
- Unknown

The VAD noise bothers me when I am awake:

- Always
- Very Often
- Sometimes
- Rarely
- Never

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

- Always
- Very Often

- Sometimes
- Rarely
- Never

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

- Always
- Very Often
- Sometimes
- Rarely
- Never

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

- Always
- Very Often
- Sometimes
- Rarely
- Never

I am bothered by how I look with the VAD:

- Always
- Very Often
- Sometimes
- Rarely
- Never

I worry about the VAD breaking or malfunctioning:

- Always
- Very Often
- Sometimes
- Rarely
- Never

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

- Always
- Very Often
- Sometimes
- Rarely
- Never

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

- Always
- Very Often
- Sometimes
- Rarely
- Never

I cannot participate in usual play activities with the VAD:

- Always
- Very Often
- Sometimes

- Rarely
- Never

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

- Always
- Very Often
- Sometimes
- Rarely
- Never

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

- High
- Between High and Medium
- Medium
- Between Low and Medium
- Low

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

- High
- Between High and Medium
- Medium
- Between Low and Medium
- Low

If No, Please select a reason why the VADQoL form was not completed:

- Too sick
- Administrative

If Administrative: Select a specific reason:

- Urgent implant, no time
- Coordinator too busy or forgot
- Unable to contact patient
- Other reason (specify)

3 Month Followup

Quality Of Life (Parent)

(QOL surveys cannot be administered after the visit date)

PedsQL

- Did the parent complete a form?**
- Yes
 - No
 - Unknown

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

PHYSICAL FUNCTIONING (problems with...)

- Walking: Walking more than one block:**
- 0 - Never
 - 1 - Almost never
 - 2 - Sometimes
 - 3 - Often
 - 4 - Almost always
 - Unknown or Not Documented

- Running: Running:**
- 0 - Never
 - 1 - Almost never
 - 2 - Sometimes
 - 3 - Often
 - 4 - Almost always
 - Unknown or Not Documented

- Participating in active play or exercise: Participating in sports activity or exercise:**
- 0 - Never
 - 1 - Almost never
 - 2 - Sometimes
 - 3 - Often
 - 4 - Almost always
 - Unknown or Not Documented

- Lifting something heavy: Lifting something heavy:**
- 0 - Never
 - 1 - Almost never
 - 2 - Sometimes
 - 3 - Often
 - 4 - Almost always
 - Unknown or Not Documented

- Bathing: Taking a bath or shower by him or herself:**
- 0 - Never
 - 1 - Almost never
 - 2 - Sometimes
 - 3 - Often
 - 4 - Almost always
 - Unknown or Not Documented

**Helping to pick up his or her toys:
Doing chores around the house:**

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

**Having hurts or aches: Having hurts
or aches:**

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Low energy level: Low energy level:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

EMOTIONAL FUNCTIONING (problems with...)

**Feeling afraid or scared: Feeling
afraid or scared:**

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

**Feeling sad or blue: Feeling sad or
blue:**

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Feeling angry: Feeling angry:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Trouble sleeping: Trouble sleeping:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

**Worrying: Worrying about what will
happen to him or her:**

- 0 - Never
- 1 - Almost never

- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

SOCIAL FUNCTIONING (problems with...)

Playing with other children: Getting along with other teens:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Other kids not wanting to play with him or her: Other teens not wanting to be his or her friend:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Getting teased by other children: Getting teased by other teens:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

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

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Keeping up when playing with other children: Keeping up when playing with other teens:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

SCHOOL FUNCTIONING (problems with...)

Paying attention in class:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Forgetting things:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes

- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Doing the same school activities as peers: Keeping up with schoolwork:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Missing school/daycare because of not feeling well: Missing school because of not feeling well:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

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

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

If No, Please select a reason why the PedsQOL was not completed:

- Too sick
- Administrative

If Administrative: Select a specific reason:

- Urgent implant, no time
- Coordinator too busy or forgot
- Unable to contact patient
- Other reason (specify)

VADQoL

Did the parent complete a form?

- Yes
- No
- Unknown

Please select the 'Parent' form:

- VADQoL: Parent (child < 2 yrs)
- VADQoL: Parent (child >= 2 yrs)

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

- Always
- Very Often
- Sometimes
- Rarely
- Never

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

- Always
- Very Often

- Sometimes
- Rarely
- Never

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

- Always
- Very Often
- Sometimes
- Rarely
- Never

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

- Always
- Very Often
- Sometimes
- Rarely
- Never

My child is bothered by how he or she looks with the VAD:

- Always
- Very Often
- Sometimes
- Rarely
- Never

My child worries about the VAD breaking or malfunctioning:

- Always
- Very Often
- Sometimes
- Rarely
- Never

My child is bothered that he or she cannot visit family or friends outside the home or hospital with the VAD:

- Always
- Very Often
- Sometimes
- Rarely
- Never

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

- Always
- Very Often
- Sometimes
- Rarely
- Never

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

- Always
- Very Often
- Sometimes

- Rarely
- Never

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

- Always
- Very Often
- Sometimes
- Rarely
- Never

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

- High
- Between High and Medium
- Medium
- Between Low and Medium
- Low

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

- High
- Between High and Medium
- Medium
- Between Low and Medium
- Low

If No, Please select a reason why the VADQoL form was not completed:

- Too sick
- Administrative

If Administrative: Select a specific reason:

- Urgent implant, no time
- Coordinator too busy or forgot
- Unable to contact patient
- Other reason (specify)

3 Month Followup

Quality Of Life (Parent)

(QOL surveys cannot be administered after the visit date)

PedsQL

- Did the parent complete a form?**
- Yes
 - No
 - Unknown

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

PHYSICAL FUNCTIONING (problems with...)

- Walking more than one block:**
- 0 - Never
 - 1 - Almost never
 - 2 - Sometimes
 - 3 - Often
 - 4 - Almost always
 - Unknown or Not Documented

- Running:**
- 0 - Never
 - 1 - Almost never
 - 2 - Sometimes
 - 3 - Often
 - 4 - Almost always
 - Unknown or Not Documented

- Participating in sports activity or exercise:**
- 0 - Never
 - 1 - Almost never
 - 2 - Sometimes
 - 3 - Often
 - 4 - Almost always
 - Unknown or Not Documented

- Lifting something heavy:**
- 0 - Never
 - 1 - Almost never
 - 2 - Sometimes
 - 3 - Often
 - 4 - Almost always
 - Unknown or Not Documented

- Taking a bath or shower by him or herself:**
- 0 - Never
 - 1 - Almost never
 - 2 - Sometimes
 - 3 - Often
 - 4 - Almost always
 - Unknown or Not Documented

Doing chores, like picking up his or her toys:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Having hurts or aches:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Low energy level:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

EMOTIONAL FUNCTIONING (problems with...)

Feeling afraid or scared:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Feeling sad or blue:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Feeling angry:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Trouble sleeping:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Worrying about what will happen to him or her:

- 0 - Never
- 1 - Almost never

- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

SOCIAL FUNCTIONING (problems with...)**Getting along with other children:**

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Other kids not wanting to be his or her friend:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Getting teased by other children:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

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

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Keeping up when playing with other children:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

SCHOOL FUNCTIONING (problems with...)**Paying attention in class:**

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Forgetting things:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes

- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Keeping up with school activities:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Missing school because of not feeling well:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Missing school to go to the doctor or hospital:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

If No, Please select a reason why the PedsQOL was not completed:

- Too sick
- Administrative

If Administrative: Select a specific reason:

- Urgent implant, no time
- Coordinator too busy or forgot
- Unable to contact patient
- Other reason (specify)

VADQoL

Did the parent complete a form?

- Yes
- No
- Unknown

Please select the 'Parent' form:

- VADQoL: Parent (child < 2 yrs)
- VADQoL: Parent (child >= 2 yrs)

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

- Always
- Very Often
- Sometimes
- Rarely
- Never

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

- Always
- Very Often

- Sometimes
- Rarely
- Never

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

- Always
- Very Often
- Sometimes
- Rarely
- Never

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

- Always
- Very Often
- Sometimes
- Rarely
- Never

My child is bothered by how he or she looks with the VAD:

- Always
- Very Often
- Sometimes
- Rarely
- Never

My child worries about the VAD breaking or malfunctioning:

- Always
- Very Often
- Sometimes
- Rarely
- Never

My child is bothered that he or she cannot visit family or friends outside the home or hospital with the VAD:

- Always
- Very Often
- Sometimes
- Rarely
- Never

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

- Always
- Very Often
- Sometimes
- Rarely
- Never

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

- Always
- Very Often
- Sometimes

- Rarely
- Never

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

- Always
- Very Often
- Sometimes
- Rarely
- Never

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

- High
- Between High and Medium
- Medium
- Between Low and Medium
- Low

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

- High
- Between High and Medium
- Medium
- Between Low and Medium
- Low

If No, Please select a reason why the VADQoL form was not completed:

- Too sick
- Administrative

If Administrative: Select a specific reason:

- Urgent implant, no time
- Coordinator too busy or forgot
- Unable to contact patient
- Other reason (specify)

3 Month Followup

Quality Of Life (Parent)

(QOL surveys cannot be administered after the visit date)

PedsQL

- Did the parent complete a form?**
- Yes
 - No
 - Unknown

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

PHYSICAL FUNCTIONING (problems with...)

- Walking more than one block:**
- 0 - Never
 - 1 - Almost never
 - 2 - Sometimes
 - 3 - Often
 - 4 - Almost always
 - Unknown or Not Documented

- Running:**
- 0 - Never
 - 1 - Almost never
 - 2 - Sometimes
 - 3 - Often
 - 4 - Almost always
 - Unknown or Not Documented

- Participating in sports activity or exercise:**
- 0 - Never
 - 1 - Almost never
 - 2 - Sometimes
 - 3 - Often
 - 4 - Almost always
 - Unknown or Not Documented

- Lifting something heavy:**
- 0 - Never
 - 1 - Almost never
 - 2 - Sometimes
 - 3 - Often
 - 4 - Almost always
 - Unknown or Not Documented

- Taking a bath or shower by him or herself:**
- 0 - Never
 - 1 - Almost never
 - 2 - Sometimes
 - 3 - Often
 - 4 - Almost always
 - Unknown or Not Documented

Doing chores, like picking up his or her toys::

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Having hurts or aches:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Low energy level:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

EMOTIONAL FUNCTIONING (problems with...)

Feeling afraid or scared:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Feeling sad or blue:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Feeling angry:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Trouble sleeping:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Worrying about what will happen to him or her:

- 0 - Never
- 1 - Almost never

- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

SOCIAL FUNCTIONING (problems with...)**Getting along with other children:**

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Other kids not wanting to be his or her friend:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Getting teased by other children:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

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

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Keeping up when playing with other children:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

SCHOOL FUNCTIONING (problems with...)**Paying attention in class:**

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Forgetting things:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes

- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Keeping up with school activities:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Missing school because of not feeling well:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Missing school to go to the doctor or hospital:

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- 1 - Almost never
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If No, Please select a reason why the PedsQOL was not completed:

- Too sick
- Administrative

If Administrative: Select a specific reason:

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- Coordinator too busy or forgot
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VADQoL

Did the parent complete a form?

- Yes
- No
- Unknown

Please select the 'Parent' form:

- VADQoL: Parent (child < 2 yrs)
- VADQoL: Parent (child >= 2 yrs)

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- Sometimes
- Rarely
- Never

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

- Always
- Very Often

- Sometimes
- Rarely
- Never

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

- Always
- Very Often
- Sometimes
- Rarely
- Never

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

- Always
- Very Often
- Sometimes
- Rarely
- Never

My child is bothered by how he or she looks with the VAD:

- Always
- Very Often
- Sometimes
- Rarely
- Never

My child worries about the VAD breaking or malfunctioning:

- Always
- Very Often
- Sometimes
- Rarely
- Never

My child is bothered that he or she cannot visit family or friends outside the home or hospital with the VAD:

- Always
- Very Often
- Sometimes
- Rarely
- Never

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

- Always
- Very Often
- Sometimes
- Rarely
- Never

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

- Always
- Very Often
- Sometimes

- Rarely
- Never

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

- High
- Between High and Medium
- Medium
- Between Low and Medium
- Low

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- High
- Between High and Medium
- Medium
- Between Low and Medium
- Low

If No, Please select a reason why the VADQoL form was not completed:

- Too sick
- Administrative

If Administrative: Select a specific reason:

- Urgent implant, no time
- Coordinator too busy or forgot
- Unable to contact patient
- Other reason (specify)

3 Month Followup

Quality Of Life (Parent)

(QOL surveys cannot be administered after the visit date)

PedsQL

- Did the parent complete a form?**
- Yes
 - No
 - Unknown

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

PHYSICAL FUNCTIONING (problems with...)

- Walking more than one block:**
- 0 - Never
 - 1 - Almost never
 - 2 - Sometimes
 - 3 - Often
 - 4 - Almost always
 - Unknown or Not Documented

- Running:**
- 0 - Never
 - 1 - Almost never
 - 2 - Sometimes
 - 3 - Often
 - 4 - Almost always
 - Unknown or Not Documented

- Participating in sports activity or exercise:**
- 0 - Never
 - 1 - Almost never
 - 2 - Sometimes
 - 3 - Often
 - 4 - Almost always
 - Unknown or Not Documented

- Lifting something heavy:**
- 0 - Never
 - 1 - Almost never
 - 2 - Sometimes
 - 3 - Often
 - 4 - Almost always
 - Unknown or Not Documented

- Taking a bath or shower by him or herself:**
- 0 - Never
 - 1 - Almost never
 - 2 - Sometimes
 - 3 - Often
 - 4 - Almost always
 - Unknown or Not Documented

Doing chores around the house:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Having hurts or aches:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Low energy level:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

EMOTIONAL FUNCTIONING (problems with...)**Feeling afraid or scared:**

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Feeling sad or blue:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Feeling angry:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Trouble sleeping:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

**Worrying about what will happen to
him or her:**

- 0 - Never
- 1 - Almost never

- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

SOCIAL FUNCTIONING (problems with...)**Getting along with other teens:**

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Other teens not wanting to be his or her friend:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Getting teased by other teens:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

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

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Keeping up when playing with other teens:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

SCHOOL FUNCTIONING (problems with...)**Paying attention in class:**

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Forgetting things:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes

- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Keeping up with schoolwork:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Missing school because of not feeling well:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Missing school to go to the doctor or hospital:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

If No, Please select a reason why the PedsQOL was not completed:

- Too sick
- Administrative

If Administrative: Select a specific reason:

- Urgent implant, no time
- Coordinator too busy or forgot
- Unable to contact patient
- Other reason (specify)

VADQoL

Did the parent complete a form?

- Yes
- No
- Unknown

Please select the 'Parent' form:

- VADQoL: Parent (child < 2 yrs)
- VADQoL: Parent (child >= 2 yrs)

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

- Always
- Very Often
- Sometimes
- Rarely
- Never

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

- Always
- Very Often

- Sometimes
- Rarely
- Never

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

- Always
- Very Often
- Sometimes
- Rarely
- Never

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

- Always
- Very Often
- Sometimes
- Rarely
- Never

My child is bothered by how he or she looks with the VAD:

- Always
- Very Often
- Sometimes
- Rarely
- Never

My child worries about the VAD breaking or malfunctioning:

- Always
- Very Often
- Sometimes
- Rarely
- Never

My child is bothered that he or she cannot visit family or friends outside the home or hospital with the VAD:

- Always
- Very Often
- Sometimes
- Rarely
- Never

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

- Always
- Very Often
- Sometimes
- Rarely
- Never

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

- Always
- Very Often
- Sometimes

- Rarely
- Never

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

- Always
- Very Often
- Sometimes
- Rarely
- Never

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

- High
- Between High and Medium
- Medium
- Between Low and Medium
- Low

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

- High
- Between High and Medium
- Medium
- Between Low and Medium
- Low

If No, Please select a reason why the VADQoL form was not completed:

- Too sick
- Administrative

If Administrative: Select a specific reason:

- Urgent implant, no time
- Coordinator too busy or forgot
- Unable to contact patient
- Other reason (specify)

Adverse Event - Pedimacs

Adverse Event Status

Please enter the date of the event you
are reporting:

Please enter a label describing this
event:

Adverse Event - Pedimacs

Rehospitalization

Was there an occurrence of rehospitalization?

- Yes
 No

Date of admission

ST= Unknown

Discharge Date

ST= Unknown

Primary reason for rehospitalization

- Anticoagulation adjustment
- Arterial Non-CNS Thrombo-embolism
- Cardiac Arrhythmia
- Cardiac Tamponade
- Catastrophe (i.e. weather)
- Device Malfunction
- Diagnostic Procedure
- Explant
- Fever without known cause
- Fluid Overload
- Gastroenteritis
- GI Disorder
- Hematological
- Hematoma
- Hemolysis
- Hepatic Dysfunction
- Hypertension
- Limb vascular complication
- Major Bleeding
- Major Infection
- Metabolic/Electrolyte Disturbance
- Myocardial Infarction
- Neurological Dysfunction
- Other, specify
- Pericardial Fluid Collection
- Planned medical management
- Planned Procedure
- Pneumonia
- Psychiatric Episode
- Pulmonary Embolism/Hemorrhage
- Pulmonary, Other
- Renal Dysfunction
- Respiratory Failure
- Right Heart Failure
- Social Issues / Disposition (Foster Care / Eviction)
- Syncope without known cause
- Transplant
- Trauma/Accident

- Unknown
 - Venous Thromboembolic Event
 - Wound Complication
 - Wound Dehiscence
-

Rehospitalization intervention

- None
- Transplantation
- Surgical Procedure
- Heart Cath
- Invasive Cardiac Procedures (Other than Heart Cath)
- Unknown
- Other

Type of surgical procedure

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

Type of other cardiac procedure

- Reoperation for Bleeding within 48 hours of implant
- Reoperation for Bleeding and/or tamponade > 48 hours
- Surgical Drainage of pericardial effusion
- Aortic Valve Surgery - Repair (no valve closure)
- Aortic Valve Surgery - Repair with valve closure
- Aortic Valve Surgery - Replacement - Biological
- Aortic Valve Surgery - Replacement - Mechanical
- Mitral Valve Surgery - Repair
- Mitral Valve Surgery - Replacement - Biological
- Mitral Valve Surgery - Replacement - Mechanical
- Tricuspid Valve Surgery - Repair - DeVega
- Tricuspid Valve Surgery - Repair - Ring
- Tricuspid Valve Surgery - Repair - Other
- Tricuspid Valve Surgery – Replacement - Biological
- Tricuspid Valve Surgery – Replacement - Mechanical
- Pulmonary Valve Surgery - Repair
- Pulmonary Valve Surgery – Replacement - Biological
- Pulmonary Valve Surgery – Replacement - Mechanical
- Other, specify
- Unknown

Type of procedure (non cardiac surgical procedure)

Other procedure

- Intubation and Vent support
- Dialysis
- Bronchoscopy
- Other, specify

Type of Invasive Cardiac Procedure (Other than Heart Cath)

Enter PA systolic pressure

 mmHg

- ST= Unknown
 Not Done

Enter PA diastolic pressure mmHg

ST= Unknown
 Not Done

Enter PCW pressure mmHg

ST= Unknown
 Not Done

Enter Cardiac output L/min

ST= Unknown
 Not Done

Clinical Observations

Systolic blood pressure mmHg

ST= Unknown
 Not done

Diastolic blood pressure mmHg

ST= Unknown
 Not done

Mean Arterial Blood Pressure (MAP) mmHg

ST= Unknown
 Not done

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

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

If yes, please enter the Modified Rankin Scale.

Modified Rankin Scale

- 0 – No symptoms at all
- 1 - No Significant disability: despite symptoms: able to carry out all usual duties and activities
- 2 - Slight disability: unable to carry out all previous activities but able to look after own affairs without assistance
- 3 - Moderate disability: requiring some help, but able to walk without assistance.
- 4 - Moderately severe disability: unable to walk without assistance, and unable to attend to own bodily needs without assistance.
- 5 - Severe disability: bedridden, incontinent and requiring constant nursing care and attention.
- 6 - Dead

ST= Not Documented
 Not Done

Adverse Event - Pedimacs

Infection

Was there a major infection?

- Yes
 No
 Unknown

Date of onset

ST= Unknown

Did this infection contribute to death?

- Yes
 No
 Unknown

Location of patient

- In hospital
 Out of hospital
 Unknown

Location of infection

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

Type of infection

- Bacterial
 Fungal
 Viral
 Protozoan
 Unknown

Intervention

- Drug therapy only: Oral
 Drug therapy only: IV
 Surgical and drug therapy
 Surgical therapy only
 Unknown

Is this a Device Related Event?

- Yes
 No

Adverse Event - Pedimacs

Bleeding (Transfusions for anemia and hemolysis are not considered bleeding events)

Was there a Major Bleeding Event?

Yes
 No
 Unknown

Date of bleeding episode onset

ST= Unknown

Location of patient

In hospital
 Out of hospital
 Unknown

Did the major bleeding episode result in one or more of the following

Episode resulted in Death
 Episode resulted in re-intervention
 Episode resulted in hospitalization
 Episode resulted in transfusion

Total units PRBC's (Enter total number of cc's received for this bleeding episode)

ST= Unknown

Date of first transfusion for this episode

ST= Unknown

Source/cause/location of bleeding

Mediastinal: chest wall
 Mediastinal: outflow-aorta anastomosis
 Mediastinal: outflow conduit
 Mediastinal: inflow conduit
 Mediastinal: aortic-venous cannulation site
 Mediastinal: coagulopathy with no surgical site
 Mediastinal: other surgical site
 Pump pocket
 Pleural space
 Intra-abdominal
 Retroperitoneal
 Pulmonary
 Device anastomosis
 Urinary tract
 GI: Upper gastrointestinal (esophagus, stomach, duodenum, small bowel)
 GI: Lower gastrointestinal (colon, rectum, and anus)
 GI: unknown, but guaiac positive stools
 Other, specify

Heparin levels

ST= Unknown

Not Done

INR

ST= Unknown

Not Done

Anticoagulant therapy at time of event

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

Is this a Device Related Event?

Yes

No

Adverse Event - Pedimacs

Neuro

Was there a neurological dysfunction?

Yes
 No
 Unknown

Date of onset

ST= Unknown

Location of patient

In hospital
 Out of hospital
 Unknown

Neurological dysfunction categories

TIA
 CVA
 Seizure
 Encephalopathy
 Infarction Seen by Imaging, without Clinical Findings of TIA/Stroke
 Extra-axial Bleeding Seen by imaging study
 Confusion
 None

Type of CVA

Ischemic / Embolism
 Hemorrhagic
 Other

Stroke severity

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

Is this a Device Related Event?

Yes
 No

Seizure Type

Generalized
 Focal

Encephalopathy type

Metabolic
 Anoxic
 Traumatic
 Other

Did this Neurological Dysfunction Adverse Event contribute to the patient's death?

Yes
 No
 Unknown

Location of CNS event

- Right hemisphere: frontal
- Right hemisphere: temporal
- Right hemisphere: occipital
- Right hemisphere: parietal
- Right hemisphere: unspecified
- Left hemisphere: frontal
- Left hemisphere: temporal
- Left hemisphere: occipital
- Left hemisphere: parietal
- Left hemisphere: unspecified
- Bilateral: frontal
- Bilateral: temporal
- Bilateral: occipital
- Bilateral: parietal
- Occipital
- Brain stem
- Cerebellar
- Thalamic
- Subdural
- Spinal cord
- Unknown
- Other, specify

Method of diagnosis of CNS event

- CT
- MRI
- Angiogram
- Clinical
- EEG
- Ultrasound
- Unknown
- Other, specify

Anticoagulant therapy at time of event

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

Hypertension

- Yes
- No
- Unknown

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

- Yes
- No
- Unknown

If yes, please enter the Modified Rankin Scale.

Modified Rankin Scale

- 0 - No symptoms at all
- 1 - No Significant disability
- 2 - Slight disability
- 3 - Moderate disability
- 4 - Moderately severe disability
- 5 - Severe disability
- 6 - Dead

ST= Not Documented
 Not Done

Adverse Event - Pedimacs

Device Malfunction/Failure and/or Pump Thrombus

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

- Yes
 No
 Unknown

Date of onset

Device Type

Location of patient

- In hospital
 Out of hospital
 Unknown

Description of Malfunction

Thrombus Event

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

- Yes
 No
 Unknown

Was the suspected or confirmed thrombus associated with one or more of the following signs or symptoms?

- Hemolysis
 Heart Failure
 Abnormal Pump Parameters
 Stroke
 TIA
 Arterial Non-CNS Thromboembolism
 None
 Other, Specify

Did the patient have one or more of the following?

- Treatment with intravenous anticoagulation (e.g. heparin)
 Intravenous thrombolytic (e.g. TPA)
 Intravenous antiplatelet therapy (e.g. eptifibatide)
 Other, Specify

Was the thrombus event confirmed?

- Yes
 No
 Unknown

Please select method of confirmation:

- Imaging Study
 Visual Inspection
 Manufacturer's Report

Was there a device Malfunction?

- Yes
 No
 Unknown

Please select all of the components that apply**Pump**

- Yes
 No

Pump Component(s)

- Pump Body (including bearings and rotor)
 Driveline
 Inflow Cannula
 Outflow Graft (including bend relief)

Controller

- Yes
 No

Controller

- Primary System Failure (running in backup mode)
 Complete System Failure (primary and backup failure)
 Power Cable (attached to controller)
 Power Connectors (attached to controller)
 Other, Specify

Peripherals

- Yes
 No

Peripheral Component(s)

- External Battery
 Cell Battery (in controller)
 Power Module
 Patient Cable
 System Monitor / Display
 Battery Charger
 Battery Clip

Pump (RVAD)

- Yes
 No

Pump Component(s) (RVAD)

- Pump Body (including bearings and rotor)
 Driveline
 Inflow Cannula
 Outflow Graft (including bend relief)

Controller (RVAD)

- Yes
 No

Controller Component(s) (RVAD)

- Primary System Failure (running in backup mode)
 Complete System Failure (primary and backup failure)
 Power Cable (attached to controller)
 Power Connectors (attached to controller)
 Other, Specify

Peripherals (RVAD)

- Yes
 No

Peripheral Component(s) (RVAD)

- External Battery
 Cell Battery (in controller)
 Power Module

- Patient Cable
- System Monitor / Display
- Battery Charger
- Battery Clip

Outcomes of Device Adverse Event

Patient Outcome

- Death
- Serious Injury
- Urgent Transplantation
- Explant Without Replacement
- Exchange
- Breach of Integrity of Drive Line that Required Repair
- Other Surgical Procedure
- None of the Above

Causative or contributing factors to the Device Malfunction

- Patient Accident
- Patient Non-Compliance
- Sub Therapeutic Anticoagulation
- Prothrombotic States
- End of Component Expected Life
- Technical and/or Procedural Issues (e.g. cannula or graft malposition or kinking)
- No Cause Identified

Adverse Event - Pedimacs

Additional Adverse Events

Were there any additional adverse events? Yes
 No

Cardiac Arrhythmia Yes
 No
 Unknown

Event Date

ST= Unknown

Type of cardiac arrhythmia Sustained ventricular arrhythmia requiring defibrillation or cardioversion
 Sustained supraventricular arrhythmia requiring drug treatment or cardioversion
 Unknown

Pericardial Effusion Yes
 No
 Unknown

Event Date

ST= Unknown

Signs of tamponade Yes
 No
 Unknown

Method of drainage OP
 Cath
 Unknown

Hepatic Dysfunction Yes
 No
 Unknown

Total bilirubin measurement mg/dL

ST= Unknown

Not Done

SGOT / AST measurement u/L

ST= Unknown

Not Done

SGPT / ALT measurement u/L

ST= Unknown

Not Done

Event Date

ST= Unknown

Myocardial Infarction

- Yes
- No
- Unknown

Event Date

ST= Unknown

Psychiatric Episode

- Yes
- No
- Unknown

Event Date

ST= Unknown

Renal Dysfunction

- Yes
- No
- Unknown

Event Date

ST= Unknown

Dialysis duration

days

ST= Unknown

- Not Done
- Ongoing

Peak creatinine measurement

mg/dL

ST= Unknown

- Not Done

Respiratory Failure

- Yes
- No
- Unknown

Event Date

ST= Unknown

- Ongoing

Intubation duration

days

ST= Unknown

- Ongoing

Was a tracheotomy performed?

- Yes
- No
- Unknown

**Arterial Non-CNS
Thromboembolism**

- Yes
- No
- Unknown

Date

ST= Unknown

Location

- Pulmonary
- Renal
- Hepatic
- Splenic
- Limb
- Other
- Unknown

Confirmation source

- Standard clinical and laboratory testing
- Operative findings
- Autopsy finding
- Other
- Unknown

Anticoagulant therapy at time of event

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

Venous Thromboembolism Event

- Deep Vein thrombosis
- Pulmonary Embolus
- Other, specify
- Unknown
- None

Enter deep vein thrombosis date

ST= Unknown

Enter pulmonary embolus date

ST= Unknown

Enter other date

ST= Unknown

Anticoagulant therapy at time of event

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

Wound Dehiscence

- Yes
- No
- Unknown

Date

ST= Unknown

Enter location:

- Sternum
- Driveline Sites
- Site of thoracotomy
- Other, specify

Other Events

- Yes
- No
- Unknown

Description

Event Date

ST= Unknown

Adverse Event - Pedimacs

Explant

Was Device Explanted for any reason (includes exchanges or "turned off")?

Yes
 No

Explant date

ST= Unknown

Device explanted LVAD

Explant reason

Explant - Death
 Explant - Transplanted
 Explant - Exchange
 Explant - No new device
 Turned off (decommissioned)

Explant reasons (check all that apply)

Device Malfunction: Elective (Please fill out Device Malfunction/Thrombus form)
 Device Malfunction: Emergent (Please fill out Device Malfunction/Thrombus form)
 Device Thrombosis: Elective (Please fill out Device Malfunction/Thrombus form)
 Device Thrombosis: Emergent (Please fill out Device Malfunction/Thrombus form)
 Infection: Elective (Please fill out Infection form)
 Infection: Emergent (Please fill out Infection form)
 Other

Exchanged Device FDA IDE Trial

Yes
 No
 Unknown

Name of FDA IDE Trial

Explant reasons (check all that apply)

Recovery
 Withdrawal of Support
 Device Malfunction: Elective (Please fill out Device Malfunction/Thrombus form)
 Device Malfunction: Emergent (Please fill out Device Malfunction/Thrombus form)
 Device Thrombosis: Elective (Please fill out Device Malfunction/Thrombus form)
 Device Thrombosis: Emergent (Please fill out Device Malfunction/Thrombus form)
 Infection: Elective (Please fill out Infection form)
 Infection: Emergent (Please fill out Infection form)
 Other

Reasons (check all that apply)

- Recovery
- Withdrawal of Support
- Device Malfunction: Elective (Please fill out Device Malfunction/Thrombus form)
- Device Malfunction: Emergent (Please fill out Device Malfunction/Thrombus form)
- Device Thrombosis: Elective (Please fill out Device Malfunction/Thrombus form)
- Device Thrombosis: Emergent (Please fill out Device Malfunction/Thrombus form)
- Infection: Elective (Please fill out Infection form)
- Infection: Emergent (Please fill out Infection form)
- Other

Evidence of Pump Thrombosis?

- Yes
- No
- Unknown

Evidence of Pump Thrombosis?

- Yes
- No
- Unknown

Transplant date

ST= Unknown

Waitlist ID

Adverse Event - Pedimacs

Death

Did the patient die? Yes
 No

Death date

ST= Unknown

Was device functioning normally? Yes
 No
 Unknown

Associated Operation Yes
 No
 Unknown

Post mortem device explant? Yes
 No
 Unknown

Did the device go to the manufacturer? Yes
 No
 Unknown

Location of death In hospital
 Long term care facility
 Home/Residence
 Out of hospital, Other
 Unknown

Primary cause of death

- Respiratory: Venous Thromboembolism Event
- Respiratory: Respiratory Failure
- Respiratory: Pulmonary: Other, specify
- Circulatory: Arterial Non-CNS Thromboembolism
- Circulatory: Myocardial Infarction
- Circulatory: Myocardial Rupture
- Circulatory: Ruptured Aortic aneurysm
- Circulatory: Right Heart Failure
- Circulatory: Major Bleeding
- Circulatory: Cardiac Arrhythmia
- Circulatory: Hemolysis
- Circulatory: Hypertension
- Circulatory: Other, Specify
- Circulatory: Sudden unexplained death
- Circulatory: CHF
- Circulatory: Heart Disease
- Circulatory: End Stage Cardiomyopathy
- Circulatory: End Stage Ischemic Cardiomyopathy
- Circulatory: Pericardial Fluid Collection (effusion)
- Digestive (Intestinal or GI/GU): Hepatic Dysfunction
- Digestive (Intestinal or GI/GU): Renal Dysfunction
- Digestive (Intestinal or GI/GU): GI Disorder
- Digestive (Intestinal or GI/GU): Fluid/Electrolyte Disorder
- Digestive (Intestinal or GI/GU): Pancreatitis
- Nervous System: Neurological Dysfunction
- Psychiatric Episode/Suicide
- Major Infection
- Device Malfunction
- Multiple System Organ Failure (MSOF)
- Withdrawal of Support, specify
- Cancer
- Wound Dehiscence
- Trauma/accident, specify
- Endocrine
- Hematological
- Other, specify

Select type of cancer

- CNS
- GI
- Lymph
- ENT
- Pulmonary
- Renal
- Breast
- Reproductive
- Skin
- Other
- Unknown

Specify support withdrawn

Specify

Demographics - Pedimacs

First Name

Middle Name

Last Name

Medical record number

SSN (last 5 digits)

ST= Not Assigned

Undisclosed

Date of Birth

Gender

Male

Female

Unknown

Ethnicity: Hispanic or Latino

Yes

No

Unknown

Race

American Indian or Alaska Native

Asian

African-American or Black

Hawaiian or other Pacific Islander

White

Unknown / Undisclosed

Other / none of the above

Is patient involved in a VAD related study?

Yes

No

Unknown

What is the name of the study?

Is this an industry sponsored post approval study?

Yes

No

Unknown

Implant Form - Pedimacs

Implant date

Payor

- Government Health Insurance
- Commercial Health Insurance
- Health Maintenance Organization
- Non-U.S. Insurance
- None / Self
- Unknown

Government:

- Medicare
- Medicaid
- State-Specific Plan
- Correctional Facility

Health Insurance Claim Number (HIC):

ST= Unknown

- Medicare Fee For Service
- Military Health Care
- Indian Health Service
- Not Applicable
- Other, specify

National Provider Identifier (NPI) Information

Operator First Name

ST= Unknown

Operator Middle Name

ST= Unknown

Operator Last Name

ST= Unknown

Operator NPI

ST= Unknown

Additional indication for VAD

- Failure to wean from CPB
- Post Cardiac Surgery
- None
- Failure to wean from ECMO

Device type

- LVAD
- RVAD
- BIVAD
- TAH

Device brand

- Berlin Heart EXCOR (paracorporeal)
- HeartWare HVAD
- HeartMate II LVAS
- HeartMate III
- HeartMate IP
- HeartMate VE
- HeartMate XVE
- Micromed DeBakey VAD - Child
- Novacor PC
- Novacor PCq
- Thoratec IVAD
- Thoratec PVAD
- Abiomed AB5000
- Abiomed BVS 5000
- Thoratec Centrimag (Levitronix)
- Thoratec Pedimag
- TandemHeart
- Biomedicus
- Maquet Rotaflow
- Sorin Revolution
- Abiomed Impella 2.5
- Abiomed Impella 5.0
- Abiomed Impella CP
- Abiomed Impella RP
- Other, Specify

Specify brand:

Surgical Approach

- Sternotomy
- Thoracotomy
- Subcostal
- Unknown
- Other, specify

LVAD: Serial Number

ST= Unknown

LVAD: cannulae location-inflow

- LA appendage
- LA interatrial groove
- LV apex
- LV diaphragmatic surface
- Unknown
- Other, specify

LVAD: cannulae size-inflow

ST= Unknown

LVAD: cannulae location-outflow

- Ascending aorta
- Descending thoracic aorta
- Abdominal aorta
- Unknown
- Subclavian
- Other, Specify

LVAD: cannulae size-outflow

ST= Unknown

LVAD: pump size

- 10 cc
- 15 cc
- 25 cc
- 30 cc
- 50 cc
- 60 cc
- 80 cc
- N/A

Device brand (RVAD)

Specify brand (RVAD):

RVAD: Serial Number

ST= Unknown

RVAD: cannulae location-inflow

- RA
- RV
- Unknown

RVAD: cannulae size-inflow

ST= Unknown

RVAD: cannulae location-outflow

- MPA (main pulmonary artery)
- LPA (left pulmonary artery)
- Conduit
- Other, Specify

RVAD: cannulae size-outflow

ST= Unknown

RVAD: pump size

- 10 cc
- 15 cc
- 25 cc
- 30 cc
- 50 cc
- 60 cc

- 80 cc
- N/A

TAH: Serial Number

ST= Unknown

Associated findings

- PFO / ASD
- Aortic Insufficiency
- Tricuspid Insufficiency
- Mechanical Valve
- None

Aortic Insufficiency

- Mild
- Moderate
- Severe

Tricuspid Insufficiency

- Mild
- Moderate
- Severe

Mechanical Valve

- Mitral Valve
- Aortic Valve
- Tricuspid Valve

Concomitant surgery

- None
- ASD closure
- PFO closure
- RVAD Implant
- RVAD Explant
- ECMO Decannulation
- CABG
- VSD closure
- IABP Removal
- Congenital cardiac surgery, other
- Aortic Valve Surgery - Repair (no valve closure)
- Aortic Valve Surgery - Repair with valve closure
- Aortic Valve Surgery - Replacement - Biological
- Aortic Valve Surgery - Replacement - Mechanical
- Mitral Valve Surgery - Repair
- Mitral Valve Surgery - Replacement - Biological
- Mitral Valve Surgery - Replacement - Mechanical
- Tricuspid Valve Surgery - Repair - DeVega
- Tricuspid Valve Surgery - Repair - Ring
- Tricuspid Valve Surgery - Repair - Other
- Tricuspid Valve Surgery - Replacement - Biological
- Tricuspid Valve Surgery - Replacement - Mechanical
- Pulmonary Valve Surgery - Repair
- Pulmonary Valve Surgery - Replacement - Biological
- Pulmonary Valve Surgery - Replacement - Mechanical
- Other, specify

Was the patient put on Cardio Bypass Pump?

- Yes
- No

CPB Time

 minutes

ST= Unknown

Was cross clamp used?

- Yes
- No
- Unknown

**Enter duration of the cross clamp
time in minutes**

- ST= Unknown
 Not Done

Was circulatory arrest required?

- Yes
- No

If yes:

 minutes

- ST= Unknown

Surgery Time

 minutes

- ST= Unknown

Implant Discharge - Pedimacs

During the implant hospitalization was the patient?

- Discharged alive with a device in place
- Died during the implant hospitalization
- Transplanted during the implant hospitalization
- Explanted due to recovery during the implant hospitalization

Patient discharged to

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

Implant Discharge

ST= Unknown

Acute care (ICU / CCU) duration of post-implant stay

 days

ST= Unknown

Intermediate / step-down care - duration of post-implant stay

 days

ST= Unknown

Date of approximate discontinuation of inotropes

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

Date of extubation

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

Intervention since implant

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

Surgical Procedures:

- Device Related Operation
- Surgical Procedure - Non Cardiac Surgical Procedure
- Surgical Procedure - Other Procedure
- Surgical Procedure - Unknown

Cardiac Surgical Procedures:

- Reoperation for Bleeding within 48 hours of implant
- Reoperation for Bleeding and/or tamponade > 48 hours
- Surgical Drainage of pericardial effusion

- Aortic Valve Surgery - Repair (no valve closure)
- Aortic Valve Surgery - Repair with valve closure
- Aortic Valve Surgery - Replacement - Biological
- Aortic Valve Surgery - Replacement - Mechanical
- Mitral Valve Surgery - Repair
- Mitral Valve Surgery - Replacement - Biological
- Mitral Valve Surgery - Replacement - Mechanical
- Tricuspid Valve Surgery - Repair - DeVega
- Tricuspid Valve Surgery - Repair - Ring
- Tricuspid Valve Surgery - Repair - Other
- Tricuspid Valve Surgery - Replacement - Biological
- Tricuspid Valve Surgery - Replacement - Mechanical
- Pulmonary Valve Surgery - Repair
- Pulmonary Valve Surgery - Replacement - Biological
- Pulmonary Valve Surgery - Replacement - Mechanical
- Other Cardiac Surgical Procedure
- Cardiac Surgical Procedure - Unknown

Other Procedures:

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

Functional Capacity

Sedated

- Yes
- No
- Unknown

Paralyzed

- Yes
- No
- Unknown

Intubated

- Yes
- No
- Unknown

Ambulating

- Yes
- No
- Unknown

Primary Nutrition

- Orally
- Per feeding tube
- TPN
- Not Applicable

Excursions

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

- Yes
- No
- Unknown
- Not Applicable

If yes, where (please select all that apply)

- Playroom
- Cafeteria
- Walk outside
- Sitting room
- General rehab
- None

Pump Change

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

- Yes
- No
- Unknown

If yes, please select one of the following:

- Intracorporeal device
- Para- or Extra- corporeal device
- Upsizing device because of patient growth status
- All other reasons would categorize the pump change as a Device Malfunction

Please select appropriate reason:

- Thrombus NOT associated with hemolysis
- Change in hemodynamics
- Clinical status
- Device parameters

Was there a Console Change?

- Yes
- No
- Unknown

Date of console change

ST= Unknown

Original Console Name

New Console Name

Transfusion

Was there a Tranfusion?

- Yes
- No
- Unknown

If yes, enter number of PRBC (Total number of cc's received)

ST= Unknown

PreImplant - Pedimacs

PreImplant Status

Demographics

Height in
 cm
 ST= Unknown
 Not Done

Weight lbs
 kg
 ST= Unknown
 Not Done

Blood Type O
 A
 B
 AB
 Unknown

Medical Support Status

Current Device Strategy at time of implant Bridge to Recovery
 Rescue Therapy
 Bridge to Transplant (patient currently listed for transplant)
 Possible Bridge to Transplant - Likely to be eligible
 Possible Bridge to Transplant - Moderate likelihood of becoming eligible
 Possible Bridge to Transplant - Unlikely to become eligible
 Destination Therapy

List Date for Transplant
 ST= Unknown

Current ICD device in place? Yes
 No
 Unknown

Patient treated for heart failure prior to admission? Yes
 No
 Unknown

Number of cardiac hospitalizations in the last 12 months 0-1
 2-3
 4 or more
 Unknown

Cardiac diagnosis / Primary

- Cancer
- Congenital Heart Disease: Biventricular: CAVC/VSD/ASD
- Congenital Heart Disease: Biventricular: Congenitally Corrected Transposition (l-TGA) (CC-TGA)
- Congenital Heart Disease: Biventricular: Ebstein's Anomaly
- Congenital Heart Disease: Biventricular: Kawasaki Disease
- Congenital Heart Disease: Biventricular: Left Heart Valve/Structural Hypoplasia
- Congenital Heart Disease: Biventricular: TOF/TOF Variant
- Congenital Heart Disease: Biventricular: Transposition of the Great Arteries (d-TGA)
- Congenital Heart Disease: Biventricular: Truncus Arteriosus
- Congenital Heart Disease: Single Ventricle: Heterotaxy / Complex CAVC
- Congenital Heart Disease: Single Ventricle: Hypoplastic Left Heart
- Congenital Heart Disease: Single Ventricle: Other
- Congenital Heart Disease: Single Ventricle: Pulmonary Artesia with IVS
- Congenital Heart Disease: Single Ventricle: Pulmonary Artesia with IVS (RVDC)
- Congenital Heart Disease: Single Ventricle: Unspecified
- Coronary Artery Disease
- Dilated Myopathy: Adriamycin
- Dilated Myopathy: Alcoholic
- Dilated Myopathy: Familial
- Dilated Myopathy: Idiopathic
- Dilated Myopathy: Ischemic
- Dilated Myopathy: Myocarditis
- Dilated Myopathy: Other, Specify
- Dilated Myopathy: Post Partum
- Dilated Myopathy: Viral
- Dilated Myopathy: LV non-compaction
- Dilated Myopathy: Unspecified
- Hypertrophic Cardiomyopathy
- Post Transplant / Graft Dysfunction
- Restrictive Myopathy: Amyloidosis
- Restrictive Myopathy: Endocardial Fibrosis
- Restrictive Myopathy: Idiopathic
- Restrictive Myopathy: Other, specify
- Restrictive Myopathy: Sarcoidosis
- Restrictive Myopathy: Sec to Radiation/Chemotherapy
- Restrictive Myopathy: Unspecified
- Valvular Heart Disease
- Unknown
- None

Dilated Myopathy: Other, Specify:

Restrictive Myopathy: Other, Specify:

Congenital Heart Disease: Single Ventricle: Other, Specify:

Cardiac diagnosis / Secondary

- Cancer
- Congenital Heart Disease: Biventricular: CAVC/VSD/ASD
- Congenital Heart Disease: Biventricular: Congenitally Corrected Transposition (l-TGA) (CC-TGA)
- Congenital Heart Disease: Biventricular: Ebstein's Anomaly
- Congenital Heart Disease: Biventricular: Kawasaki Disease
- Congenital Heart Disease: Biventricular: Left Heart Valve/Structural Hypoplasia
- Congenital Heart Disease: Biventricular: TOF/TOF Variant
- Congenital Heart Disease: Biventricular: Transposition of the Great Arteries (d-TGA)
- Congenital Heart Disease: Biventricular: Truncus Arteriosus
- Congenital Heart Disease: Single Ventricle: Heterotaxy / Complex CAVC
- Congenital Heart Disease: Single Ventricle: Hypoplastic Left Heart
- Congenital Heart Disease: Single Ventricle: Other
- Congenital Heart Disease: Single Ventricle: Pulmonary Artesia with IVS
- Congenital Heart Disease: Single Ventricle: Pulmonary Artesia with IVS (RVDC)
- Congenital Heart Disease: Single Ventricle: Unspecified
- Coronary Artery Disease
- Dilated Myopathy: Adriamycin
- Dilated Myopathy: Alcoholic
- Dilated Myopathy: Familial
- Dilated Myopathy: Idiopathic
- Dilated Myopathy: Ischemic
- Dilated Myopathy: Myocarditis
- Dilated Myopathy: Other, Specify
- Dilated Myopathy: Post Partum
- Dilated Myopathy: Viral
- Dilated Myopathy: LV non-compaction
- Dilated Myopathy: Unspecified
- Hypertrophic Cardiomyopathy
- Post Transplant / Graft Dysfunction
- Restrictive Myopathy: Amyloidosis
- Restrictive Myopathy: Endocardial Fibrosis
- Restrictive Myopathy: Idiopathic
- Restrictive Myopathy: Other, specify
- Restrictive Myopathy: Sarciodosis
- Restrictive Myopathy: Sec to Radiation/Chemotherapy
- Restrictive Myopathy: Unspecified
- Valvular Heart Disease
- Unknown
- None

Dilated Myopathy: Other, Specify:

Restrictive Myopathy: Other, Specify:

Congenital Heart Disease: Single Ventricle: Other, Specify:

Previous cardiac operation

- None
- CABG
- Aneurymectomy (DOR)
- Aortic Valve replacement / repair
- Mitral valve replacement / repair
- Tricuspid replacement /repair
- Congenital cardiac surgery
- LVAD
- RVAD

- TAH
- Previous heart transplant
- Previous ECMO
- Other, specify (INCLUDE ONLY OPERATIONS ACTUALLY PERFORMED ON HEART OR GREAT VESSELS)

**Congenital cardiac surgery,
Check all that apply**

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

**Admitting Diagnosis or Planned
Implant**

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

- GI (Nausea, vomiting, diarrhea)
- Respiratory (SOB, wheezing, respiratory failure)
- FTT
- Lethargy
- Other, specify:

**Clinical Events and Interventions
this hospitalization (Pre-implant)**

- CABG
- Aortic Valve replacement / repair
- Mitral valve replacement / repair
- Congenital cardiac surgery
- Other surgical procedures
- IABP
- ECMO
- LVAD
- RVAD
- TAH
- Dialysis
- Ultrafiltration
- Feeding tube
- Intubation
- Major MI
- Major infections / Positive blood cultures
- Unknown
- None
- Escalation to CPAP
- Arrythmia
- Previous ECMO
- Previous heart transplant
- Treatment of Rejection
- Peritoneal Drain
- Non-cardiac procedure

Select Type of infection:

- Bacterial
- Fungal
- Viral
- Protozoan
- Unknown

Select Location of infection:

- Blood
- Endocarditis, native
- Line Sepsis
- Mediastinum
- Pneumonia
- Urine
- Unknown
- Other

**Congenital cardiac surgery,
Select all that apply:**

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

Primary Reason: Clinical manifestation of heart failure prompting VAD insertion according to the implanting physician:

- Decline in renal function
- Decline in hepatic function
- Decline in respiratory function
- Refractory fluid retention / volume overload
- Decline in cardiac output (by exam, mixed venous saturation, or cath) prior to onset of worsening acidosis/lactate
- Decline in nutrition / feeding intolerance
- Incessant severe sinus tachycardia
- Worsening tachyarryhythmia
- Other, please specify
- Not Reported

Select all that apply:

- Emesis or inadequate calories (<70% prescribed) requiring enteral feeding tube placement
- Recurrent emesis with adequate caloric intake despite feeding tube placement
- Inadequate caloric intake (with or without emesis) despite feeding tube placement
- Requiring parenteral (IV) nutrition

Secondary Reason(s): Clinical manifestation of heart failure prompting VAD insertion according to the implanting physician:

- Decline in renal function
- Decline in hepatic function
- Decline in respiratory function
- Refractory fluid retention / volume overload
- Decline in cardiac output (by exam, mixed venous saturation, or cath) prior to onset of worsening acidosis/lactate
- Decline in nutrition / feeding intolerance
- Incessant severe sinus tachycardia
- Worsening tachyarryhythmia
- Other, please specify
- Not Reported

Select all that apply:

- Emesis or inadequate calories (<70% prescribed) requiring enteral feeding tube placement
- Recurrent emesis with adequate caloric intake despite feeding tube placement
- Inadequate caloric intake (with or without emesis) despite feeding tube placement
- Requiring parenteral (IV) nutrition

IV inotrope therapy within 48 hours of implant

- Yes
- No
- Unknown

If Yes, IV inotrope therapy agents:

- Dobutamine
- Dopamine
- Milrinone
- Levosimendan
- Epinephrine
- Norepinephrine
- Isoproterenol
- Vasopressin
- Nitroprusside
- Fenoldopam
- Nesiritide
- Other, Specify
- Unknown

Is this implant the primary MCSD (LVAD or TAH) for this patient?

- Yes
- No

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

PEDIMACS® Patient Profile at time of implant

- 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 (see the Site Users Guide, Section II. 2.4 Pre-Implant Form, PEDIMACS Patient Profiles for more details)
- 2 "Progressive decline" describes a patient who has been demonstrated "dependent" on inotropic support but nonetheless shows signs of continuing deterioration (see the Site Users Guide, Section II. 2.4 Pre-Implant Form, PEDIMACS Patient Profiles for more details)
- 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 symptoms (see the Site Users Guide, Section II. 2.4 Pre-Implant Form, PEDIMACS Patient Profiles for more details)
- 4 "Resting symptoms" describes a patient who is at home on oral therapy but frequently has symptoms of congestion at rest or with ADL. (see the Site Users Guide, Section II. 2.4 Pre-Implant Form, PEDIMACS Patient Profiles for more details)
- 5 "Exertion Intolerant" describes a patient who is comfortable at rest but unable to engage in any activity, living predominantly within the house or household (see the Site Users Guide, Section II. 2.4 Pre-Implant Form, PEDIMACS Patient Profiles for more details)
- 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 (see the Site Users Guide, Section II. 2.4 Pre-Implant Form, PEDIMACS Patient Profiles for more details)
- 7 "Advanced NYHA Class 3" or "Ross Class III" describes a patient who is clinically stable with a reasonable level of comfortable activity, despite history of previous decompensation that is not recent (see the Site Users Guide, Section II. 2.4 Pre-Implant Form, PEDIMACS Patient Profiles for more details)

MODIFIERS of the PEDIMACS® Patient Profiles

- A - Arrhythmia.**
- Yes
 - No
 - Unknown

- TCS –Temporary Circulatory Support.**
- Yes
 - No
 - Unknown

- FF – Frequent Flyer.**
- Yes
 - No
 - Unknown

Best Functional Capacity within 24 hours of Implant

- Sedated**
- Yes
 - No
 - Unknown

- Paralyzed**
- Yes
 - No
 - Unknown

- Intubated**
- Yes
 - No

Unknown

Ambulating

Yes

No

Unknown

Primary Nutrition

Orally

Per feeding tube

TPN

Not Applicable

PreImplant - Pedimacs

Hemodynamics

Hemodynamics

Systolic blood pressure mmHg

ST= Unknown
 Not done

Diastolic blood pressure mmHg

ST= Unknown
 Not done

Peripheral edema Yes
 No
 Unknown

Ascites Yes
 No
 Unknown

ECG rhythm Sinus
 Atrial fibrillation
 Atrial Flutter
 Paced: Atrial pacing
 Paced: Ventricular pacing
 Paced: Atrial and ventricular pacing
 Unknown
 Not done
 Other, specify

Echo Findings

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

Right AV Regurgitation 0 (none)
 1 (mild)
 2 (moderate)
 3 (severe)
 Not Recorded or Not Documented
 Not Applicable

Aortic regurgitation

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

System Ventricle Ejection Fraction

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

Left Ventricular Shortening Fraction

- Normal
- Mild
- Moderate
- Severe
- Not Done or Not Available

LVEDD

 cm

ST= Not Recorded or Not Documented

RVEF

- Normal
- Mild
- Moderate
- Severe
- Not Done
- Not Applicable
- Unknown

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

Was there a thrombus identified by Echo?

- Yes
- No

Select all that apply:

- RA - Right Atrium
- RV - Right Ventricle
- LA - Left Atrium
- LV - Left Ventricle
- SVC - Superior Vena Cava
- IVC - Inferior Vena Cava
- Unknown

Invasive Hemodynamics

Date of measurement:

ST= Unknown
 Not Done

Heart rate beats per minute

ST= Unknown
 Not Done

Pulmonary Artery Systolic Pressure mmHg

ST= Unknown
 Not Done

Pulmonary Artery Diastolic Pressure mmHg

ST= Unknown
 Not Done

RA Pressure mmHg

ST= Unknown
 Not Done

PVR wood units

ST= Unknown
 Not Done

Pulmonary wedge pressure mmHg

ST= Unknown
 Not Done

Cardiac index L/min/m²

ST= Unknown
 Not Done

Was Cardiac Index Measured by Fick or Thermodilution?
 Yes
 No
 Unknown

Choose Method
 Fick
 Thermodilution

PreImplant - Pedimacs

Laboratory

Sodium mEq/L
 mmol/L
 ST= Unknown
 Not done

Potassium mEq/L
 mmol/L
 ST= Unknown
 Not done

Blood urea nitrogen mg/dL
 mmol/L
 ST= Unknown
 Not done

Creatinine mg/dL
 umol/L
 ST= Unknown
 Not done

SGPT/ALT (alanine aminotransferase/ALT) u/L
 ST= Unknown
 Not done

SGOT/AST (aspartate aminotransferase/AST) u/L
 ST= Unknown
 Not done

LDH units/L, U/L, ukat/L
 ST= Unknown
 Not done

Total bilirubin mg/dL
 umol/L
 ST= Unknown
 Not done

Bilirubin direct mg/dL
 umol/L
 ST= Unknown
 Not Done

Bilirubin indirect

mg/dL
 umol/L

ST= Unknown
 Not Done

Albumin

g/dL
 g/L

ST= Unknown
 Not done

Pre-albumin

mg/dL
 mg/L

ST= Unknown
 Not done

Total Cholesterol

mg/dL
 mmol/L

ST= < 50 mg/dL
 Unknown
 Not done

Brain natriuretic peptide BNP

pg/mL
 ng/L

ST= > 7500 pg/mL
 Unknown
 Not done

NT pro brain natriuretic peptide Pro-BNP

pg/mL
 ng/L

ST= Unknown
 Not done

White blood cell count

x10³/uL
 x10⁹/L

ST= Unknown
 Not done

Reticulocyte count

%

ST= Unknown
 Not Done

Hemoglobin

g/dL
 g/L
 mmol/L

ST= Unknown
 Not done

Hemoglobin A1C

%

mmol/mol

Estimated Average Glucose (eAG):

mg/dL

mmol/L

ST= Unknown

Not Done

Platelets

x10³/uL

x10⁹/L

ST= Unknown

Not done

INR

international units

ST= Unknown

Not done

Uric acid

mg/dL

umol/L

ST= <1 mg/dL

Unknown

Not done

Lymphocyte Count

%

x10³ cells/μL

x10⁹ cells/liter

ST= Unknown

Not done

<2%

Lupus Anticoagulant

Positive

Negative

Unknown

PreImplant - Pedimacs

Concerns and Contraindications

Concerns / Contraindications	Is condition present?		Limitation for transplant listing?	
	Yes	No	Yes	No
Overall Status				
Patient does not want transplant	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Musculoskeletal limitation to ambulation	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Contraindication to immunosuppression	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Allosensitization	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Frailty	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Chronic Renal Disease	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Cardiothoracic issues				
Frequent ICD Shocks	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Pulmonary Disease	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Pulmonary Hypertension	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Recent Pulmonary Embolus	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
History Of Atrial Arrhythmia	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Unfavorable Mediastinal Anatomy (includes sternotomies, sternal resection, radiation, flail chest, etc)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Thoracic Aortic Disease	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Tracheostomy	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Plastic Bronchitis	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Nutritional/GI				
Large BMI	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Severe Diabetes	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Malnutrition Cachexia	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
History Of GI Ulcers	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
History Of Hepatitis	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Liver Dysfunction	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Anasarca	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Protein Losing enteropathy	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Genetic Syndrome	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Vascular issues				
Heparin Induced Thrombocytopenia	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Chronic Coagulopathy	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Major Stroke	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Other Cerebrovascular Disease

Peripheral Vascular Disease

Oncology/infection issues	Yes	No	Unknown	Yes	No
History Of Solid Organ Cancer	<input type="radio"/>	<input type="radio"/>		<input type="radio"/>	<input type="radio"/>
History Of Lymphoma Leukemia	<input type="radio"/>	<input type="radio"/>		<input type="radio"/>	<input type="radio"/>
History Of Bone Marrow Transplant BMT	<input type="radio"/>	<input type="radio"/>		<input type="radio"/>	<input type="radio"/>
History Of HIV	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Chronic Infectious Concerns	<input type="radio"/>	<input type="radio"/>		<input type="radio"/>	<input type="radio"/>

Psychosocial issues (If patient is < 10 years old at the time of implant, based on chart review of the patient, are the conditions present or absent?)

	Yes	No	Unknown	Yes	No
Limited Cognition/Understanding	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Limited Social Support	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Repeated Noncompliance	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
History Of Illicit Drug Use	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
History Of Alcohol Abuse	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Narcotic Dependence	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
History Of Smoking	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Currently Smoking	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Severe Depression	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other Major Psychiatric Diagnosis	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Neurological // developmental abnormalities	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other Comorbidity	<input type="radio"/>	<input type="radio"/>		<input type="radio"/>	<input type="radio"/>

HIV History

HIV Diagnosis Date

ST= Unknown
 Not Done

Plasma HIV-1 RNA (Viral load) - Closest to implant copies/ml

ST= Not Done

CD4 T-Cell Count - Closest to implant cells/mm3

ST= Not Done

Erythrocyte Sedimentation Rate (ESR) mm/hr

ST= Not Done

C-Reactive Protein (CRP) mg/L

ST= Not Done

Antiretroviral Therapy

- Abacavir (ABC) / Ziagen
- Atripla (FTC/EDV/TDF)
- Atazanavir (ATV) / Reyataz
- Combivir (3TC/ZDV)
- Complera (FTC/RPV/TDF)
- Darunavir (DRV) / Prezista
- Delavirdine (DLV) / Rescriptor
- Didanosine (ddI) / Videx EC
- Dolutegravir / Tivicay
- Efavirenz (EFV) / Sustiva
- Emtricitabine (FTC) / Emtriva
- Enfuvirtide (T20) / Fuzeon
- Epzicom (3TC/ABC)
- Etravirine (ETR) / Intelence
- Fosamprenavir (FPV) / Lexiva
- Indinavir (IDV) / Crixivan
- Kaletra (LPV/r)
- Lamivudine (3TC) / EpiVir
- Maraviroc (MVC) / Selzentry
- Nelfinavir (NFV) / Viracept
- Nevirapine (NVP) / Viramune / Viramune XR
- Raltegravir (RAL) / Isentress
- Rilpivirine (RPV) / Edurant
- Ritonavir (RTV) / Norvir
- Saquinavir (SQV) / Invirase
- Stavudine (d4T) / Zerit
- Stribild (FTC/EVG/COBI/TDF)
- Tenofovir Disoproxil Fumarate (TDF) / Viread
- Tipranavir (TPV) / Aptivus
- Trizivir (3TC/ZDV/ABC)
- Truvada (FTC/TDF)
- Zidovudine (ZDV) / Retrovir
- Unknown
- None

Infection Prophylaxis

- Atovaquone
- Azithromycin
- Dapsone
- Fluconazole
- Pentamidine, aerosolized
- Trimethoprim-sulfamethoxazole (TMP-SMX)
- Unknown
- None

History of Opportunistic Infection

- Cryptococcosis
- Cytomegalovirus (CMV)
- Epstein Barr virus (EBV)
- Esophageal candidiasis
- Histoplasmosis
- Kaposi's sarcoma
- Mycobacterium avium complex (MAC), disseminated
- Pneumocystis jiroveci (carinii) pneumonia (PCP)
- Toxoplasmosis
- Tuberculosis
- None

History of Hepatitis B

- Positive
- Negative

ST= Unknown

Not Done

History of Hepatitis C

Positive

Negative

ST= Unknown

Not Done

PreImplant - Pedimacs

Medications

Loop diuretics

- Yes
- No
- Unknown

If yes, enter dosage

mg/day

ST= Unknown

Type of Loop Diuretic:

- Furosemide
- Torsemide
- Bumetanide
- Other

**Cardiac Resynchronization Therapy
(CRT)**

- Yes
- No
- Unknown

Preimplant - Pedimacs

Quality Of Life

(QOL surveys cannot be administered after the visit date)

PedsQL

- Did the child complete a form?**
- Yes
 - No
 - Unknown

- Please select the 'Child' form:**
- PedsQL Young Child (5-7 yrs)
 - PedsQL Child (8-12 yrs)
 - PedsQL Teen (13-18 yrs)

PHYSICAL FUNCTIONING (problems with...)

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

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

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

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

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

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

- Do you have hurts or aches:**
- 0 - Not at all
 - 2 - Sometimes
 - 4 - A lot
 - Unknown or Not Documented

Where?

Do you ever feel too tired to play:

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

EMOTIONAL FUNCTIONING (problems with...)

Do you feel scared:

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

Do you feel sad:

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

Do you feel mad:

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

Do you have trouble sleeping:

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

Do you worry about what will happen to you:

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

SOCIAL FUNCTIONING (problems with...)

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

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

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

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

Do other kids tease you:

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

Can other kids do things that you cannot do:

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

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

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

SCHOOL FUNCTIONING (problems with...)

Is it hard for you to pay attention in class:

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

Do you forget things:

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

Is it hard to keep up with schoolwork:

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

Do you miss school because of not feeling good:

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

Do you miss school because you have to go to the doctor's or hospital:

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

If No, Please select a reason why the PedsQOL was not completed:

- Too sick
- Administrative

If Administrative: Select a specific reason:

- Urgent implant, no time
- Coordinator too busy or forgot
- Unable to contact patient
- Other reason (specify)

Preimplant - Pedimacs

Quality Of Life

(QOL surveys cannot be administered after the visit date)

PedsQL

- Did the child complete a form?**
- Yes
 - No
 - Unknown

- Please select the 'Child' form:**
- PedsQL Young Child (5-7 yrs)
 - PedsQL Child (8-12 yrs)
 - PedsQL Teen (13-18 yrs)

ABOUT MY HEALTH AND ACTIVITES (problems with...)

- It is hard for me to walk more than one block:**
- 0 - Never a problem
 - 1 - Almost never a problem
 - 2 - Sometimes a problem
 - 3 - Often a problem
 - 4 - Almost always a problem
 - Unknown or Not Documented

- It is hard for me to run:**
- 0 - Never a problem
 - 1 - Almost never a problem
 - 2 - Sometimes a problem
 - 3 - Often a problem
 - 4 - Almost always a problem
 - Unknown or Not Documented

- It is hard for me to do sports activity or exercise:**
- 0 - Never a problem
 - 1 - Almost never a problem
 - 2 - Sometimes a problem
 - 3 - Often a problem
 - 4 - Almost always a problem
 - Unknown or Not Documented

- It is hard for me to lift something heavy:**
- 0 - Never a problem
 - 1 - Almost never a problem
 - 2 - Sometimes a problem
 - 3 - Often a problem
 - 4 - Almost always a problem
 - Unknown or Not Documented

- It is hard for me to take a bath or shower by myself:**
- 0 - Never a problem
 - 1 - Almost never a problem
 - 2 - Sometimes a problem
 - 3 - Often a problem
 - 4 - Almost always a problem
 - Unknown or Not Documented

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

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

I hurt or ache:

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

Where?

I have low energy:

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

ABOUT MY FEELINGS (problems with...)

I feel afraid or scared:

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

I feel sad or blue:

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

I feel angry:

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

I have trouble sleeping:

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

I worry about what will happen to me:

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

HOW I GET ALONG WITH OTHERS (problems with...)

I have trouble getting along with other kids:

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

Other kids do not want to be my friend:

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

Other kids tease me:

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

I cannot do things other kids my age can do:

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

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

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

ABOUT SCHOOL (problems with...)

Is it hard to pay attention in class:

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

I forget things:

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

I have trouble keeping up with my schoolwork:

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

I miss school because of not feeling well:

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

I miss school to go to the doctor or hospital:

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

If No, Please select a reason why the PedsQOL was not completed:

- Too sick
- Administrative

If Administrative: Select a specific reason:

- Urgent implant, no time
- Coordinator too busy or forgot
- Unable to contact patient
- Other reason (specify)

Prelimplant - Pedimacs

Quality Of Life

(QOL surveys cannot be administered after the visit date)

PedsQL

- Did the child complete a form?**
- Yes
 - No
 - Unknown

- Please select the 'Child' form:**
- PedsQL Young Child (5-7 yrs)
 - PedsQL Child (8-12 yrs)
 - PedsQL Teen (13-18 yrs)

ABOUT MY HEALTH AND ACTIVITES (problems with...)

- It is hard for me to walk more than one block:**
- 0 - Never a problem
 - 1 - Almost never a problem
 - 2 - Sometimes a problem
 - 3 - Often a problem
 - 4 - Almost always a problem
 - Unknown or Not Documented

- It is hard for me to run:**
- 0 - Never a problem
 - 1 - Almost never a problem
 - 2 - Sometimes a problem
 - 3 - Often a problem
 - 4 - Almost always a problem
 - Unknown or Not Documented

- It is hard for me to do sports activity or exercise:**
- 0 - Never a problem
 - 1 - Almost never a problem
 - 2 - Sometimes a problem
 - 3 - Often a problem
 - 4 - Almost always a problem
 - Unknown or Not Documented

- It is hard for me to lift something heavy:**
- 0 - Never a problem
 - 1 - Almost never a problem
 - 2 - Sometimes a problem
 - 3 - Often a problem
 - 4 - Almost always a problem
 - Unknown or Not Documented

- It is hard for me to take a bath or shower by myself:**
- 0 - Never a problem
 - 1 - Almost never a problem
 - 2 - Sometimes a problem
 - 3 - Often a problem
 - 4 - Almost always a problem
 - Unknown or Not Documented

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

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

I hurt or ache:

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

Where?

I have low energy:

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

ABOUT MY FEELINGS (problems with...)

I feel afraid or scared:

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

I feel sad or blue:

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

I feel angry:

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

I have trouble sleeping:

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

I worry about what will happen to me:

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

HOW I GET ALONG WITH OTHERS (problems with...)

I have trouble getting along with other teens:

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

Other teens do not want to be my friend:

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

Other teens tease me:

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

I cannot do things other teens my age can do:

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

It is hard to keep up with peers:

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

ABOUT SCHOOL (problems with...)

Is it hard to pay attention in class:

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

I forget things:

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

I have trouble keeping up with my schoolwork:

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

I miss school because of not feeling well:

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

I miss school to go to the doctor or hospital:

- 0 - Never a problem
- 1 - Almost never a problem
- 2 - Sometimes a problem
- 3 - Often a problem
- 4 - Almost always a problem
- Unknown or Not Documented

If No, Please select a reason why the PedsQOL was not completed:

- Too sick
- Administrative

If Administrative: Select a specific reason:

- Urgent implant, no time
- Coordinator too busy or forgot
- Unable to contact patient
- Other reason (specify)

Prelimplant - Pedimacs

Quality Of Life (Parent)

(QOL surveys cannot be administered after the visit date)

PedsQL

- Did the parent complete a form?**
- Yes
 - No
 - Unknown

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

PHYSICAL FUNCTIONING (problems with...)

- Walking: Walking more than one block:**
- 0 - Never
 - 1 - Almost never
 - 2 - Sometimes
 - 3 - Often
 - 4 - Almost always
 - Unknown or Not Documented

- Running: Running:**
- 0 - Never
 - 1 - Almost never
 - 2 - Sometimes
 - 3 - Often
 - 4 - Almost always
 - Unknown or Not Documented

- Participating in active play or exercise: Participating in sports activity or exercise:**
- 0 - Never
 - 1 - Almost never
 - 2 - Sometimes
 - 3 - Often
 - 4 - Almost always
 - Unknown or Not Documented

- Lifting something heavy: Lifting something heavy:**
- 0 - Never
 - 1 - Almost never
 - 2 - Sometimes
 - 3 - Often
 - 4 - Almost always
 - Unknown or Not Documented

- Bathing: Taking a bath or shower by him or herself:**
- 0 - Never
 - 1 - Almost never
 - 2 - Sometimes
 - 3 - Often
 - 4 - Almost always
 - Unknown or Not Documented

**Helping to pick up his or her toys:
Doing chores around the house:**

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

**Having hurts or aches: Having hurts
or aches:**

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Low energy level: Low energy level:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

EMOTIONAL FUNCTIONING (problems with...)

**Feeling afraid or scared: Feeling
afraid or scared:**

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

**Feeling sad or blue: Feeling sad or
blue:**

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Feeling angry: Feeling angry:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Trouble sleeping: Trouble sleeping:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

**Worrying: Worrying about what will
happen to him or her:**

- 0 - Never
- 1 - Almost never

- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

SOCIAL FUNCTIONING (problems with...)

Playing with other children: Getting along with other teens:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Other kids not wanting to play with him or her: Other teens not wanting to be his or her friend:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Getting teased by other children: Getting teased by other teens:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

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

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Keeping up when playing with other children: Keeping up when playing with other teens:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

SCHOOL FUNCTIONING (problems with...)

Paying attention in class:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Forgetting things:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes

- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Doing the same school activities as peers: Keeping up with schoolwork:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Missing school/daycare because of not feeling well: Missing school because of not feeling well:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

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

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

If No, Please select a reason why the PedsQOL was not completed:

- Too sick
- Administrative

If Administrative: Select a specific reason:

- Urgent implant, no time
- Coordinator too busy or forgot
- Unable to contact patient
- Other reason (specify)

Prelimplant - Pedimacs

Quality Of Life (Parent)

(QOL surveys cannot be administered after the visit date)

PedsQL

- Did the parent complete a form?**
- Yes
 - No
 - Unknown

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

PHYSICAL FUNCTIONING (problems with...)

- Walking more than one block:**
- 0 - Never
 - 1 - Almost never
 - 2 - Sometimes
 - 3 - Often
 - 4 - Almost always
 - Unknown or Not Documented

- Running:**
- 0 - Never
 - 1 - Almost never
 - 2 - Sometimes
 - 3 - Often
 - 4 - Almost always
 - Unknown or Not Documented

- Participating in sports activity or exercise:**
- 0 - Never
 - 1 - Almost never
 - 2 - Sometimes
 - 3 - Often
 - 4 - Almost always
 - Unknown or Not Documented

- Lifting something heavy:**
- 0 - Never
 - 1 - Almost never
 - 2 - Sometimes
 - 3 - Often
 - 4 - Almost always
 - Unknown or Not Documented

- Taking a bath or shower by him or herself:**
- 0 - Never
 - 1 - Almost never
 - 2 - Sometimes
 - 3 - Often
 - 4 - Almost always
 - Unknown or Not Documented

Doing chores, like picking up his or her toys:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Having hurts or aches:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Low energy level:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

EMOTIONAL FUNCTIONING (problems with...)

Feeling afraid or scared:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Feeling sad or blue:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Feeling angry:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Trouble sleeping:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Worrying about what will happen to him or her:

- 0 - Never
- 1 - Almost never

- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

SOCIAL FUNCTIONING (problems with...)

Getting along with other children:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Other kids not wanting to be his or her friend:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Getting teased by other children:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

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

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Keeping up when playing with other children:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

SCHOOL FUNCTIONING (problems with...)

Paying attention in class:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Forgetting things:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes

- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Keeping up with school activities:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Missing school because of not feeling well:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Missing school to go to the doctor or hospital:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

If No, Please select a reason why the PedsQOL was not completed:

- Too sick
- Administrative

If Administrative: Select a specific reason:

- Urgent implant, no time
- Coordinator too busy or forgot
- Unable to contact patient
- Other reason (specify)

Prelimplant - Pedimacs

Quality Of Life (Parent)

(QOL surveys cannot be administered after the visit date)

PedsQL

- Did the parent complete a form?**
- Yes
 - No
 - Unknown

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

PHYSICAL FUNCTIONING (problems with...)

- Walking more than one block:**
- 0 - Never
 - 1 - Almost never
 - 2 - Sometimes
 - 3 - Often
 - 4 - Almost always
 - Unknown or Not Documented

- Running:**
- 0 - Never
 - 1 - Almost never
 - 2 - Sometimes
 - 3 - Often
 - 4 - Almost always
 - Unknown or Not Documented

- Participating in sports activity or exercise:**
- 0 - Never
 - 1 - Almost never
 - 2 - Sometimes
 - 3 - Often
 - 4 - Almost always
 - Unknown or Not Documented

- Lifting something heavy:**
- 0 - Never
 - 1 - Almost never
 - 2 - Sometimes
 - 3 - Often
 - 4 - Almost always
 - Unknown or Not Documented

- Taking a bath or shower by him or herself:**
- 0 - Never
 - 1 - Almost never
 - 2 - Sometimes
 - 3 - Often
 - 4 - Almost always
 - Unknown or Not Documented

Doing chores around the house:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Having hurts or aches:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Low energy level:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

EMOTIONAL FUNCTIONING (problems with...)

Feeling afraid or scared:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Feeling sad or blue:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Feeling angry:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Trouble sleeping:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Worrying about what will happen to him or her:

- 0 - Never
- 1 - Almost never

- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

SOCIAL FUNCTIONING (problems with...)

Getting along with other children:

- 0 - Never
- 1 - Almost never
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- 3 - Often
- 4 - Almost always
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Other kids not wanting to be his or her friend:

- 0 - Never
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- 3 - Often
- 4 - Almost always
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Getting teased by other children:

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- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

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

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Keeping up when playing with other children:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

SCHOOL FUNCTIONING (problems with...)

Paying attention in class:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Forgetting things:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes

- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Keeping up with schoolwork:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Missing school because of not feeling well:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Missing school to go to the doctor or hospital:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
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Prelimplant - Pedimacs

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 - PedsQL Child (8-12 yrs)
 - PedsQL Teen (13-18 yrs)

PHYSICAL FUNCTIONING (problems with...)

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- 3 - Often
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EMOTIONAL FUNCTIONING (problems with...)

Feeling afraid or scared:

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- 3 - Often
- 4 - Almost always
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- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
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Feeling angry:

- 0 - Never
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- 3 - Often
- 4 - Almost always
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Trouble sleeping:

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- 4 - Almost always
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Worrying about what will happen to him or her:

- 0 - Never
- 1 - Almost never

- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

SOCIAL FUNCTIONING (problems with...)

Getting along with other teens:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Other teens not wanting to be his or her friend:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Getting teased by other teens:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

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

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Keeping up when playing with other teens:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

SCHOOL FUNCTIONING (problems with...)

Paying attention in class:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Forgetting things:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes

- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Keeping up with schoolwork:

- 0 - Never
- 1 - Almost never
- 2 - Sometimes
- 3 - Often
- 4 - Almost always
- Unknown or Not Documented

Missing school because of not feeling well:

- 0 - Never
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- Administrative

If Administrative: Select a specific reason:

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- Coordinator too busy or forgot
- Unable to contact patient
- Other reason (specify)

PreImplant - Pedimacs

Exercise Function

All patients ≥ 10 years of age at time of implant should attempt to complete these functional capacity measurements especially for those patients classified as Intermacs patient profile level 4-7

6 minute walk

feet

ST= Not done

Not done: too sick

Not done: other

Not done: age inappropriate

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

Gait Speed (1st 15 foot walk)

seconds

ST= Not done

Not done: too sick

Not done: other

Not done: age inappropriate

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

Peak VO2 Max

mL/kg/min

ST= Not done

Not done: too sick

Not done: other

Not done: age inappropriate

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

R Value at peak

%

ST= Not done

Not done: too sick

Not done: other

Not done: age inappropriate

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

Medical Condition

NYHA Class

Class I: No limitation of physical activity; physical activity does not cause fatigue, palpitation or shortness of breath.

Class II: Slight limitation of physical activity; comfortable at rest, but ordinary physical activity results in fatigue, palpitations or shortness of

breath.

- Class III: Marked limitation of physical activity; comfortable at rest, but less than ordinary activity causes fatigue, palpitation or shortness of breath.
- Class IV: Unable to carry on minimal physical activity without discomfort; symptoms may be present at rest.
- Unknown

Ross Classification of Congestive Heart Failure

- Ross Class I: No limitations or symptoms.
- Ross Class II: No growth failure.
- Ross Class III: Growth failure.
- Ross Class IV: Symptomatic at rest.
- Not applicable: ≥ 2 years of age
- Unknown

Choose all indicated symptoms that apply.

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

Choose all indicated symptoms that apply.

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

Choose all indicated symptoms that apply.

- Tachypnea
- Retractions
- Grunting
- Diaphoresis
- Unknown

Screening Log - Pedimacs

Implant Date

Inclusion: Patient must meet all inclusion criteria:

- Patient less than 19 years of age at time of implant
- Patient receives a mechanical circulatory support device (MCSD) which is FDA approved
- Implanted on or after September 19, 2012 (The device does not need to be the first implant for the patient)
- Patient signed informed consent for the registry

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

- Patient 19 years or older at time of implant (patient should be enrolled in INTERMACS)
- Patient receives an (MCSD) which is not FDA approved
- Patient is incarcerated (prisoner)
- Patient did not sign the informed consent

Device type

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

Device brand

- Berlin Heart EXCOR (paracorporeal)
- HeartWare HVAD
- HeartMate II LVAS
- HeartMate III
- HeartMate IP
- HeartMate VE
- HeartMate XVE
- Micromed DeBakey VAD - Child
- Novacor PC
- Novacor PCq
- Thoratec IVAD
- Thoratec PVAD
- Abiomed AB5000
- Abiomed BVS 5000
- Thoratec Centrimag (Levitronix)
- Thoratec Pedimag
- TandemHeart
- Biomedicus
- Maquet Rotaflow
- Sorin Revolution
- Abiomed Impella 2.5
- Abiomed Impella 5.0
- Abiomed Impella CP
- Abiomed Impella RP
- Other, Specify

Specify brand

Device brand (RVAD)**Specify brand (RVAD)****Age Range**

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

Race

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

Ethnicity: Hispanic or Latino

- Yes
- No
- Unknown

Gender

- Male
- Female
- Unknown

Did death occur within 2 days post implant?

- Yes
- No

Is this VAD an investigational device?

- Yes
- No

Is patient involved in a VAD related study?

- Yes
- No
- Unknown

What is the name of the study?**Is this an industry sponsored post approval study?**

- Yes
- No
- Unknown

Transfer Form - Pedimacs

Transferred Care to another hospital

- Yes
- No

Date transferred care

ST= Unknown

Withdraw Consent - Pedimacs

Did the patient withdraw consent?

- Yes
- No

Date of withdrawn consent: