

Was there a device malfunction?*

YES NO UNK

Device type:*

Date of onset:*

mm/dd/yyyy

ST=

Location of patient:*

In hospital Out of hospital Unknown

Major pump unit involved (check all that apply):*

Blood Pump
 Drive Unit Failure
 External Control System Failure
 Device Thrombosis

Blood Pump Specify:*

Drive Unit Failure Specify:*

External Control System Failure Specify:*

Device Thrombosis Specify:*

Specific component affected (check all that apply):*

External Battery Malfunction
 Internal Battery Malfunction
 External Controller Malfunction
 Internal Controller Malfunction
 Driveline Malfunction
 Inflow Graft Malfunction/Malposition
 Outflow Graft Malfunction/Malposition
 Pump Drive Unit Malfunction
 TET System Malfunction
 Inflow Valve
 Outflow Valve
 Volume Compensator Malfunction
 Other Component Malfunction, specify

External Battery Specify:*

Internal Battery Specify:*

External Controller Specify:*

Internal Controller Specify:*

Driveline Specify:*

Inflow Graft Specify:*

Outflow Graft Specify:*

Pump Drive Unit Specify:*

TET System Specify:*

Inflow Valve Specify:*

Outflow Valve Specify:*

Volume Compensator Specify:*

Other, specify:*

Causative or contributing factors to the Device Malfunction (check all that apply):*

Patient noncompliance in device maintenance and protection
 Patient error in caring for system
 Inadequate instructions from caregivers
 No specific contributing cause identified

Device malfunction intervention (check all that apply):*

Replacement of Internal Battery
 Replacement of External Battery
 Replacement of External Controller
 Replacement of Internal Controller
 Replacement of Driveline
 Replacement of Inflow Graft
 Replacement of Outflow Graft

Replacement of Pump
Replacement of TET System
Replacement of Pump Valve
Replacement of Volume Compensator
Replacement of Other Component, specify
Switch from Vented Electric to Pneumatic-mode
Other Interventions, specify
None
Unknown

Specify component: *

Other, specify: *

Surgical procedure required: *	YES	NO	UNK
Device explanted: *	YES	NO	UNK
Device malfunction adverse event cause patient's death: *	YES	NO	UNK